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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 225

RIN 0584–AE72

Streamlining Program Requirements and Improving Integrity in the Summer Food Service Program; Correction

AGENCY: Food and Nutrition Service (FNS), Department of Agriculture (USDA).

ACTION: Correcting amendments.

SUMMARY: The Food and Nutrition Service (FNS) is correcting regulations that published in a final rule in the **Federal Register** of September 19, 2022, and went into effect in the Code of Federal Regulations (CFR) on October 1, 2022. The rule amended the Summer Food Service Program (SFSP) regulations to strengthen program integrity by clarifying, simplifying, and streamlining program administration to facilitate compliance with program requirements.

DATES: Effective December 27, 2022.

FOR FURTHER INFORMATION CONTACT: Anne Fiala, 703–305–2590, *anne.fiala@usda.gov.*

SUPPLEMENTARY INFORMATION: The final rule that appeared in the **Federal Register** on September 19, 2022 (87 FR 57304), included non-substantive revisions to the introductory text of 7 CFR 225.16(d) that made the text consistent with other reverences in part 225 and used plain language. In making this change, paragraphs (d)(1) through (3) of § 225.16 were inadvertently removed leaving only the introductory text of § 225.16(d). This document corrects that error and restores the entirety of § 225.16(d). To conform with current **Federal Register** requirements, tables found in these restored paragraphs are revised to include headings that note their citation in 7 CFR part 225.

In addition, the definition of ''documentation'' in § 225.2 is renumbered to reflect the correct paragraph structure requirements for the Code of Federal Regulations. Finally, a separate, special memorandum will be issued in the future to correct a formatting error in table 1 to paragraph (e)(6)(iv) of § 225.7.

List of Subjects in 7 CFR Part 225

Food assistance programs, Grant programs—health, Infants and children, Labeling, Reporting and recordkeeping requirements.

Accordingly, for reasons stated in the preamble, FNS amends 7 CFR part 225 by making the following technical corrections:

PART 225—SUMMER FOOD SERVICE PROGRAM

■ 1. The authority citation for part 225 continues to read as follows:

Authority: Secs. 9, 13 and 14, Richard B. Russell National School Lunch Act, as amended (42 U.S.C. 1758, 1761 and 1762a).

■ 2. In § 225.2, revise the definition of ''Documentation'' to read as follows:

§ 225.2 Definitions.

* * * * *

Documentation means:

(1) The completion of the following information on a free meal application:

(i) Names of all household members;

(ii) Income received by each household member, identified by source of income (such as earnings, wages, welfare, pensions, support payments, unemployment compensation, social security and other cash income);

(iii) The signature of an adult household member; and

(iv) The last four digits of the Social Security number of the adult household member who signs the application, or an indication that the adult does not possess a Social Security number; or

(2) For a child who is a member of a household receiving SNAP, FDPIR, or TANF benefits, ''documentation'' means completion of only the following information on a free meal application:

(i) The name(s) and appropriate SNAP, FDPIR, or TANF case number(s) for the child(ren); and

(ii) The signature of an adult member of the household.

* * * * *

■ 3. In § 225.16, revise paragraph (d) to read as follows:

§ 225.16 Meal service requirements.

* * * * *

(d) *Meal patterns.* The meal requirements for the Program are designed to provide nutritious and well-balanced meals to each child. Sponsors must ensure that meals served meet all of the requirements. Except as otherwise provided in this section, the following tables present the minimum requirements for meals served to children in the Program. Children age 12 and up may be served larger portions based on the greater food needs of older children.

(1) *Breakfast.* The minimum amount of food components to be served as breakfast are as follows:

BILLING CODE 3410–30–P

Table 1 to paragraph (d)(1)	
Food components	**Minimum amount**
Vegetables and Fruits	
Vegetable(s) and/or fruit(s) or	½ cup.[1]
Full-strength vegetable or fruit juice or an equivalent quantity of any combination of vegetable(s), fruits(s), and juice	½ cup (4 fluid ounces).
Bread and Bread Alternates[2]	
Bread or	1 slice.
Cornbread, biscuits, rolls, muffins, etc. or	1 serving.[3]
Cold dry cereal or	¾ cup or 1 ounce.[4]
Cooked cereal or cereal grains or	½ cup.
Cooked pasta or noodle products or an equivalent quantity of any combination of bread/bread alternate	½ cup.
Milk[5]	
Milk, fluid	1 cup (½ pint, 8 fluid ounces).
Meat and Meat Alternates (Optional)	
Lean meat or poultry or fish or	1 ounce.
Alternate protein product[6] or	1 ounce.
Cheese or	1 ounce.
Egg (large) or	½ .
Cooked dry beans or peas or	¼ cup.
Peanut butter or an equivalent quantity of any combination of meat/meat alternate or	2 tablespoons.
Yogurt, plain or flavored, unsweetened or sweetened	4 ounces or ½ cup.

[1]For the purposes of the requirement outlined in this table, a cup means a standard measuring cup.
[2]Bread, pasta or noodle products, and cereal grains (such as rice, bulgur, or corn grits) shall be whole-grain or enriched; cornbread, biscuits, rolls, muffins, etc., shall be made with whole-grain or enriched meal or flour; cereal shall be whole-grain, enriched or fortified.
[3]Serving sizes and equivalents will be in guidance materials to be distributed by FNS to State agencies.
[4]Either volume (cup) or weight (ounces), whichever is less.
[5]Milk shall be served as a beverage or on cereal or used in part for each purpose.
[6]Must meet the requirements in appendix A of this part.

(2) *Lunch or supper.* The minimum amounts of food components to be served as lunch or supper are as follows:

Table 2 to paragraph (d)(2)	
Food components	**Minimum amount**
Meat and Meat Alternates	
Lean meat or poultry or fish or	2 ounces.
Alternate protein products[1] or	2 ounces.
Cheese or	2 ounces.
Egg (large) or	1.
Cooked dry beans or peas or	½ cup.[2]
Peanut butter or soynut butter or other nut or seed butters or	4 tablespoons.
Peanuts or soynuts or tree nuts or seed[3] or	1 ounce = 50%.[4]
Yogurt, plain or flavored, unsweetened or sweetened or an equivalent quantity of any combination of the above meat/meat alternates	8 ounces or 1 cup.
Vegetables and Fruits	
Vegetable(s) and/or fruit(s)[5]	¾ cup total.
Bread and Bread Alternatives[6]	
Bread or	1 slice.
Cornbread, biscuits, rolls, muffins, etc. or	1 serving.[7]
Cooked pasta or noodle products or	½ cup.
Cooked cereal grains or an equivalent quantity of any combination of bread/bread alternate	½ cup.
Milk	
Milk, fluid, served as a beverage	1 cup (½ pint, 8 fluid ounces).

[1]Must meet the requirements of appendix A of this part.
[2]For the purposes of the requirement outlined in this table, a cup means a standard measuring cup.
[3]Tree nuts and seeds that may be used as meat alternate are listed in program guidance.
[4]No more than 50% of the requirement shall be met with nuts or seeds. Nuts or seeds shall be combined with another meat/meat alternate to fulfill the requirement. For purposes of determining combinations, 1 ounce of nuts or seeds is equal to 1 ounce of cooked lean meat, poultry or fish.
[5]Serve 2 or more kinds of vegetable(s) and/or fruits or a combination of both. Full strength vegetable or fruit juice may be counted to meet not more than one-half of this requirement.
[6]Bread, pasta or noodle products, and cereal grains (such as rice, bulgur, or corn grits) shall be whole-grain or enriched; cornbread, biscuits, rolls, muffins, etc., shall be made with whole-grain or enriched meal or flour; cereal shall be whole-grain, enriched or fortified.
[7]Serving sizes and equivalents will be in guidance materials to be distributed by FNS to State agencies.

(3) *Snacks.* The minimum amounts of food components to be served as snacks are as follows. Select two of the following four components. (Juice may not be served when milk is served as the only other component.)

Table 3 to paragraph (d)(3)	
Food components	**Minimum amount**
Meat and Meat Alternates	
Lean meat or poultry or fish or	1 ounce.
Alternate protein products[1] or	1 ounce.
Cheese or	1 ounce.
Egg (large) or	½ .
Cooked dry beans or peas or	¼ cup[2].
Peanut butter or soynut butter or other nut or seed butters or	2 tablespoons.
Peanuts or soynuts or tree nuts or seeds[3] or	1 ounce.
Yogurt, plain or flavored, unsweetened or sweetened or an equivalent quantity of any combination of the above meat/meat alternates	4 ounce or ½ cup.
Vegetables and Fruits	
Vegetable(s) and/or fruit(s) or	¾ cup.
Full-strength vegetable or fruit juice or an equivalent quantity or any combination of vegetable(s), fruits(s) and juice	¾ cup (6 fluid ounces).
Bread and Bread Alternates[4]	
Bread or	1 slice.
Cornbread, biscuits, rolls, muffins, etc. or	1 serving.[5]
Cold dry cereal or	¾ cup or 1 ounce.[6]
Cooked cereal or	½ cup.
Cooked cereal grains or an equivalent quantity of any combination of bread/bread alternate	½ cup.
Milk[7]	
Milk, fluid	1 cup (½ pint, 8 fluid ounces).

[1]Must meet the requirements in appendix A of this part.
[2]For the purposes of the requirement outlined in this table, a cup means a standard measuring cup.
[3]Tree nuts and seeds that may be used as meat alternates are listed in program guidance.
[4]Bread, pasta or noodle products, and cereal grains (such as rice, bulgur, or corn grits) shall be whole-grain or enriched; cornbread, biscuits, rolls, muffins, etc., shall be made with whole-grain or enriched meal or flour; cereal shall be whole-grain, enriched or fortified.
[5]Serving sizes and equivalents will be in guidance materials to be distributed by FNS to State agencies.
[6]Either volume (cup) or weight (ounces), whichever is less.
[7]Milk should be served as a beverage or on cereal, or used in part for each purpose.

* * * * *

Cynthia Long,

Administrator, Food and Nutrition Service.

[FR Doc. 2022–28103 Filed 12–23–22; 8:45 am]

BILLING CODE 3410–30–C

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2022–0144]

RIN 3150–AK87

List of Approved Spent Fuel Storage Casks: NAC International, Inc. MAGNASTOR® Storage System, Certificate of Compliance No. 1031, Amendment No. 10

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of January 18, 2023, for the direct final rule that was published in the **Federal Register** on November 4, 2022. This direct final rule amended the NAC International, Inc. MAGNASTOR® Storage System listing within the list of approved spent fuel storage casks to include Amendment No. 10 to Certificate of Compliance No. 1031.

DATES: The effective date of January 18, 2023, for the direct final rule published November 4, 2022 (87 FR 66539), is confirmed.

ADDRESSES: Please refer to Docket ID NRC–2022–0144 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–2022–0144. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The final amendment to the certificate of compliance, final changes to the technical specifications, and final safety evaluation report can also be viewed in ADAMS under Accession No. ML22349A467.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. eastern time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Bernard White, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–6577, email: *Bernard.White@nrc.gov* and Tyler Hammock, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–1381, email: *Tyler.Hammock@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: On November 4, 2022 (87 FR 66539), the NRC published a direct final rule amending its regulations in part 72 of title 10 of the *Code of Federal Regulations* to revise the NAC International, Inc. MAGNASTOR® Storage System listing in the ''List of approved spent fuel storage casks'' by adding Amendment No. 10 to Certificate of Compliance No. 1031. Amendment No. 10 incorporates a new metal storage overpack. In the direct final rule, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on January 18, 2023. The NRC did not receive any comments on the direct final rule. Therefore, this direct final rule will become effective as scheduled.

Dated: December 20, 2022.

For the Nuclear Regulatory Commission.

Cindy K. Bladey,

Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2022–28025 Filed 12–23–22; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1253

RIN 2590–AA17

Prior Approval for Enterprise Products

AGENCY: Federal Housing Finance Agency.

ACTION: Final rule.

SUMMARY: The Federal Housing Finance Agency (FHFA or Agency) is adopting a final rule that establishes a process for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises) to provide advance notice to the FHFA Director before offering a new activity to the market and to obtain prior approval from the Director before offering a new product to the market.

DATES: This final rule is effective February 27, 2023.

FOR FURTHER INFORMATION CONTACT: Susan Cooper, Senior Policy Analyst, Office of Housing and Regulatory Policy, (202) 649–3121, *susan.cooper@fhfa.gov;* or Dinah Knight, Assistant General Counsel, Office of General Counsel, (202) 748–7801, *dinah.knight@fhfa.gov,* Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. These are not toll-free numbers. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Background

In recognition of the significant impact that the activities of the Enterprises have on the U.S. housing finance system, market participants, and the broader economy, section 1321 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (12 U.S.C. 4501 *et seq.*) (the Safety and Soundness Act or Act) requires the FHFA Director to review new Enterprise activities and to approve new Enterprise products before these activities and products can be offered to the market.

Specifically, the Act requires an Enterprise to provide ''written notice'' to the Director for a determination of whether a new activity is a new product subject to prior approval under section 1321. *See* section 1321(e)(2) of the Safety and Soundness Act (12 U.S.C. 4541(e)(2)). If the Director determines that the new activity is a new product,

the Enterprise shall ''obtain the approval of the Director . . . before initially offering the product.'' *See* section 1321(a) of the Safety and Soundness Act (12 U.S.C. 4541(a)). In considering any request for approval of a new product, the Director shall determine whether the proposed new product is authorized pursuant to certain sections of the Enterprises' authorizing statutes,[1] in the public interest, and consistent with the safety and soundness of the Enterprise or the mortgage finance system. *See* section 1321(b) of the Safety and Soundness Act (12 U.S.C. 4541(b)).

Certain activities are excluded from the review and approval requirements under the Act, including: (1) the Enterprises' automated loan underwriting systems as in existence on July 30, 2008 (AUS), and any upgrades to the technology, operating systems, or software to operate the underwriting systems; (2) any modifications to mortgage terms and conditions or underwriting criteria relating to mortgages that are purchased or guaranteed by an Enterprise but that do not alter the nature of the underlying transaction as residential mortgage financing; and (3) activities that are substantially similar to the activities in (1) and (2) and to new products that have been approved by the Director (substantially similar activities). *See* section 1321(e) of the Safety and Soundness Act (12 U.S.C. 4541(e)). The Act prescribes timeframes for FHFA to complete its review and to provide the public with notice and an opportunity to comment on a proposed new product. *See* sections 1321(c) and (e) of the Safety and Soundness Act (12 U.S.C. 4541(c) and (e)).

B. The Interim Final Rule and Notice of Proposed Rulemaking

FHFA adopted an interim final rule for Prior Approval for Enterprise Products which became effective on July 2, 2009, and which remains in effect until the effective date of this final rule. *See* interim final rule, 12 CFR part 1253.[2] On November 9, 2020, FHFA published in the **Federal Register** a Notice of Proposed Rulemaking on Prior Approval for Enterprise Products (Proposed Rule) that, if finalized, would replace the interim final rule. *See* Proposed Rule, 85 FR 71276. FHFA requested public comment on all aspects of the Proposed Rule. The final rule reflects adoption, clarifications, or changes based on the comments received, as well as other technical and conforming changes. A full discussion of the comments received, the Agency's responses, and a section-by-section analysis of the final rule are included in the subsequent sections.

II. Discussion of Comments and Agency Response

A. Overview of Comments Received

FHFA received 17 comments on the Proposed Rule. Commenters included the Enterprises, National Association of Home Builders, National Taxpayer Union, American Enterprise Institute, Community Home Lenders Association, National Association of Federal Credit Unions, American Bankers Association, Mortgage Bankers Association, Center for Responsible Lending, Independent Community Bankers of America, Housing Policy Council, U.S. Mortgage Insurers, National Association of Realtors, Manufactured Housing Institute, Consumer Federation of America, and one lender. Most commenters were generally supportive of the Proposed Rule and many suggested areas where it could be improved or clarified.

Comments received and FHFA's responses are summarized by topic below. In general, commenters raised concerns with the proposed submission process for a new activity, one aspect of which provided that the determination of whether a new activity was a new product would be subject to Agency discretion. Some commenters praised the explicit inclusion of pilots in the scope of a new activity while also sharing their concerns about how pilots are conducted by the Enterprises. Other commenters preferred that pilots be excluded from the requirements of the final rule. Several commenters suggested further changes to the descriptions of a new activity and a new product, including an expansion of the exclusions to reference technology that assists the Enterprises in performing their core functions. Commenters also suggested additional public interest factors that should be considered when evaluating a new product, particularly within the context of the impact of a proposed new product on competition. Many commenters also noted that the Proposed Rule, unlike the interim final rule, did not include a provision for requesting confidential treatment of information submitted to FHFA. Lastly, commenters recommended that the final rule impose on FHFA a requirement to report on the Enterprises' new activity submissions and FHFA's decisions on those submissions.

B. FHFA Determination and Approval of a New Product

Submission Process. FHFA proposed a notice process that would have required an Enterprise to make a single submission for a new activity and a new product (notice of new activity). FHFA would evaluate the notice and determine whether the new activity was subject to prior approval as a new product. The Director would make the new product determination based on whether the new activity merited public notice and comment on matters of compliance with the Enterprise's authorizing statute, safety and soundness of the Enterprise or the mortgage finance system, or serving the public interest. FHFA also proposed streamlined and simplified content for the notice of new activity that consolidated interrelated content from the sets of instructions in the interim final rule but would still be sufficient to conduct a complete assessment of associated risks and to weigh those risks against the benefits to public interest.

Commenters had varying views on the submission process. Two commenters supported the proposed submission process, with one noting that the scope of information was sufficient and guidelines for submission were appropriate ''and should help FHFA develop public notices that provide potential commenters with relevant information about future Enterprise activities.'' However, other commenters expressed concerns with and/or provided recommendations for the submission process. First, many found the breadth of information requested for a new activity disproportionately burdensome since only advance notice to FHFA is required by statute. These commenters instead viewed the scope of information as more appropriate for a request for prior approval of a new product. One commenter observed that the Proposed Rule requires the same information, at the same level of detail, for a new activity and for a new product. Another commenter urged FHFA to develop a streamlined process to permit the Enterprises to submit new activities to FHFA without the extensive detail required for new products. Commenters also believed that the valuable time and resources used to prepare detailed notices for new activities would inhibit the Enterprises' ability to pursue initiatives. In addition, the Enterprises believed that requiring an executive officer to certify that the notice of new activity did not contain material misrepresentations or

[1] Fannie Mae's authorizing statute is the Federal National Mortgage Association Charter Act (12 U.S.C. 1716 *et seq.*). Freddie Mac's authorizing statute is the Federal Home Loan Mortgage Corporation Act (12 U.S.C. 1451 *et seq.*).

[2] 74 FR 31602 (July 2, 2009).

omissions was unduly burdensome for a new activity (but not a new product) because it would entail establishing processes and dedicating resources to support such a certification. One Enterprise asserted that ''robust internal controls are sufficient to ensure quality submissions [for a new activity] without the need for an accuracy and completeness certification to FHFA.''

Next, commenters recommended that the Enterprises, not FHFA, should make the initial determination on whether a new activity is a new product. Under that approach, the Enterprise would need to determine whether to submit either a notice of new activity or a request for prior approval of a new product. One commenter believed that the ''. . . enhanced definitions of a new activity and a new product in the proposed rule are sufficient for an Enterprise to make that determination.'' The commenter recommended that FHFA re-introduce from the interim final rule the concept of an Enterprise consulting with FHFA prior to submitting a notice of new activity to determine whether a new activity is a new product. Another commenter stated that ''. . . whether FHFA ultimately adopts a one- or two-step submission process, the final rule should make clear that an Enterprise may withdraw a submission at any time.''

Lastly, some commenters expressed concerns about the level of discretion that the Director would have in determining whether a new activity was a new product. One commenter argued that the discretionary authority granted to the Director in the Proposed Rule appeared to circumvent Congress's requirement that all Enterprise offerings classified as new products be subject to public notice and comment. Other commenters were concerned that the discretion granted under the final rule could result in opaque decision-making.

After careful consideration, FHFA is modifying the submission process to address commenters' concerns about burden. FHFA agrees with commenters that the information required for FHFA to review a new activity (versus a new product) can be distinguished without compromising FHFA's ability to complete its assessment. FHFA also agrees that even for the review of a new product the information requirements could be further streamlined. The final rule reflects changes accordingly. These changes should alleviate some of the burden associated with the submission process and conserve valuable resources at the Enterprises, as well as FHFA. However, FHFA disagrees with the Enterprises' assertion that requiring an executive officer to certify to the accuracy of a new activity submission is unduly burdensome and will retain that requirement in the final rule. As stated by one Enterprise, it already has robust internal controls and governance processes for developing and offering a new activity, and these controls and processes invariably involve an executive officer's judgement, expertise, and approval. Therefore, FHFA does not believe it is an undue burden to require an executive officer to certify to the accuracy of the information contained in a notice of new activity.

In terms of allowing an Enterprise to make the initial determination whether to provide prior notice of a new activity or request prior approval for a new product, FHFA still believes that it is not practical to require an Enterprise to identify in advance a new product—as distinct from a new activity that is not a new product—for purposes of determining which type of submission to make to the Agency. The Act does not provide definitions for a product or an activity. As a result, the Proposed Rule provided distinguishing characteristics to implement the statutory mandate for the Director to approve a new product prior to an Enterprise offering that product. The statutory standard for approving a new product includes determinations that the product complies with an Enterprise's authorizing statute, is in the public interest, and is consistent with the safety and soundness of the Enterprise or the mortgage finance system. *See* section 1321(b) of the Safety and Soundness Act (12 U.S.C. 4541(b)). Because of the lack of statutory definitions, and the breadth of the statutory considerations relevant to approval, FHFA concludes that a more precise definition of a new product is not feasible, and that the Director must be able to consider each new activity, and whether that new activity should be deemed a new product, based on a broad consideration of all the facts and circumstances it presents.[3]

However, FHFA agrees that the final rule should have an explicit provision that allows an Enterprise to consult with FHFA prior to submitting a notice of new activity. If, based on that consultation, the Director determines that a new activity is a new product, then the review process could be expedited. FHFA believes that including a consultation provision and pairing it with abbreviated submission requirements for new activities and more detailed information requirements for new products (that still reflect streamlining of the information requirements from the Proposed Rule) should facilitate the Enterprises' compliance with the final rule. Further, even though the Proposed Rule implicitly permitted an Enterprise to withdraw a submission at any time, FHFA has also included language in the final rule that explicitly permits an Enterprise to discontinue its efforts to pursue a new activity once the Director has determined it to be a new product.

Timeframes for FHFA Review and Public Comment Period. FHFA proposed that before commencing any new activity, an Enterprise must submit a notice of new activity, which would not be considered complete and received for processing until the information required by the Proposed Rule had been submitted, including any follow-up information requested by FHFA. After FHFA deemed the submission complete and received, the Director would have 15 days to determine whether the new activity was a new product. If the Director determined that the new activity was a new product, FHFA would publish a public notice soliciting comments on the new product for a 30-day period. The Director would approve or disapprove the proposed new product no later than 30 days after the close of the public comment period. The Proposed Rule defined ''days'' as calendar days. The 15 days for FHFA to review a new activity and make a new product determination, the 30-day public comment period, and the 30 days for FHFA to complete its review of a proposed new product following the close of the public comment period are established by statute. The Act also provides that the Enterprise may offer the new activity or new product to the market if FHFA does not render a decision within the statutory timeframes for review.

Several commenters noted that the Proposed Rule did not provide specific timeframes for FHFA to deem a submission complete or publish a notice for public comment once the Director determined that a new activity was a new product and recommended that the final rule include such timeframes. One commenter stated that ''[a]llowing FHFA unlimited time to notify the Enterprises that a submission is complete and received practically renders moot the expedited 15-day review,'' and that this unlimited time period should be reconsidered. Another commenter argued that the 15-day period for a new activity review should

[3] When adopting the interim final rule, FHFA concluded that ''the determination whether a new activity is a new product in specific instances is committed to agency discretion by law,'' 74 FR 31602, 31603 (July 2, 2009). *See Samuels* v. *FHFA,* 54 F. Supp. 3d 1328 (S.D. Fla. 2014).

start the day that FHFA receives the notice and that ''the period should be tolled . . . any time FHFA determines a submission to be incomplete . . . resuming only when the Enterprise delivers the information requested.'' Another commenter believed that the final rule should establish a specific timeframe for FHFA to prepare a public notice, stating that ''at most, a five business-day deadline for FHFA to publish the public notice should provide FHFA with a reasonable period to prepare the notice based on the information provided by the Enterprise.'' A few commenters also recommended that the final rule have a comment period longer than 30 days. One commenter recommended that FHFA ''provide, within the statutory constraints, the public with more time to provide comments on new products'' by excluding ''all weekends and holidays (as is the current practice under the interim final rule).''

After considering these comments, FHFA is not including in the final rule specific timeframes for deeming a submission complete and received or for publishing a public notice. However, FHFA will act expeditiously in its review of a submission, and the final rule states that FHFA will publish a public notice ''without delay.'' FHFA recognizes that the Act is designed to ensure that FHFA moves quickly in its review. However, the Agency also recognizes that it has a responsibility to conduct due diligence and review a submission to ensure that the Enterprise has provided the required information for the Director to make the determination of whether a new activity is a new product. Similarly, FHFA believes that it has a responsibility to carefully prepare a notice for public comment that accurately reflects the Enterprise's proposed new product and provides the public with enough information to provide meaningful comments. Regarding comments to extend the public notice and comment period, FHFA will apply the practice it uses when publishing proposed and final regulations, which is to publish the public notice on the Agency's website the same day that it submits it to the **Federal Register**. Given that the **Federal Register** is unlikely to publish the public notice for a new product immediately, the public will have the opportunity to preview the notice on FHFA's website before the comment period officially begins.

Standards for Approval. In line with the Act, FHFA proposed that the Director may approve a new product if the Director determined that it was authorized under the relevant sections of the Enterprise's charter, in the public interest, and consistent with the safety and soundness of the Enterprise or the mortgage finance system. Two commenters recommended enhancements to the final rule that would also create explicit review standards for a new activity. One commenter suggested that a new activity should be subject to review under four standards: (1) any applicable law; (2) the Director's safety and soundness authority; (3) an Enterprise's authorizing statute; and (4) the public interest, and that the final rule should give equal weight to safety and soundness and the public interest. Another commenter recommended that FHFA establish ''a list of questions to evaluate the product or activity[, which] would provide a baseline that would ensure more consistent and objective evaluation of the public interest . . .''

After considering these comments, FHFA is not changing the standards for approval. The standards for approval of a new product are established by statute. These standards are not weighted, as suggested by one commenter, and are considered comprehensively. The Act does not establish standards for approval for a new activity because unlike a new product, a new activity need not be approved by the Director but instead is reviewed to determine whether it is a new product. As noted by commenters, FHFA has the authority to review new activities and new products under any applicable regulation or statute, as part of FHFA's authority to review for safety and soundness and for consistency with an Enterprise's statutory mission. Also, FHFA believes that establishing a list of questions to review a new activity or approve a new product is duplicative of the public interest factors that are to be considered by the Director in determining whether a new activity is a new product and in determining whether to approve a proposed new product. The public interest factors are discussed in more detail in Section D below.

C. New Activity and New Product

Scope of New Activity. FHFA proposed that an ''activity'' is a business line, business practice, offering or service, including a guarantee, a financial instrument, consulting, or marketing, that the Enterprise provides to the market, and defined it as a ''new'' activity if the Enterprise is not engaged in the activity as of the effective date of the final rule or if the Enterprise enhances, alters, or modifies an existing activity. In addition, the Proposed Rule required that a new activity must be described by one or more of the following criteria: (1) requires a new type of resource, type of data, policy, or modification to an existing policy, process, or infrastructure; (2) expands the scope or increases the level of credit risk, market risk, or operational risk to the Enterprise; (3) involves a new category of borrowers, investors, counterparties, or collateral; (4) substantially impacts the mortgage finance system, the Enterprise's safety and soundness, compliance with the Enterprise's authorizing statute, or the public interest; (5) is a pilot; or (6) results from a pilot. FHFA specifically requested comment on whether the criteria were unambiguous, transparent, and sufficient for identifying a new activity, and if not, how they could be improved.

When responding to FHFA's questions, commenters fell into two distinct groups. Some commenters believed the criteria to be unambiguous and sufficient for identifying a new activity, while other commenters did not. Among the former, one commenter viewed the criteria as ''inclusive of most scenarios that [an Enterprise] could possibly face when adding a new activity or product.'' Another commenter supported the more objective approach to identifying new activities as contained in the Proposed Rule rather than relying solely on exclusions as had been done in the interim final rule. However, other commenters viewed the criteria as overly broad and in need of clarification. One commenter stated that the ''definition of new activity should not be so broad that it includes every minor deviation of an existing program or small process/policy changes.'' Other commenters, including the Enterprises, were concerned that the criteria could capture a large volume of routine activities, including revisions and updates to internal risk management policies and selling and servicing guides. Some commenters recommended that FHFA clarify the criteria by including a materiality standard or re-introducing qualifiers from the interim final rule, such as ''significantly,'' ''*de minimis,*'' or numerical thresholds, to ensure that immaterial increases in risk do not trigger notification under the final rule.

FHFA purposely designed the criteria to be broad because, as recognized by a few commenters, the Agency's review of new activities functions as a screening process for identifying new products. While FHFA is not changing the criteria to narrow their scope, FHFA agrees that certain changes to improve clarity are appropriate and would enhance

Enterprise compliance with the final rule.

FHFA is not adopting the commenters' suggestions to add qualifying language or numerical thresholds to the criteria because the suggestions do not resolve the issues that FHFA identified with the interim final rule. In the Proposed Rule, FHFA sought not only to describe what is a new activity (rather than what is *not* a new activity as was the case in the interim final rule) but also to establish objective criteria that distinguish a new activity from an on-going activity. Furthermore, FHFA believes that it is difficult to measure and consistently apply numerical thresholds or other qualifiers such as ''*de minimis,*'' across all Enterprise business lines, business practices, offerings, and services.

Exclusions. In conjunction with the proposed criteria for identifying a new activity, the Proposed Rule incorporated the statutory exclusions from the review and approval requirements of the Act. The Proposed Rule described the statutory exclusions, which are either the specific activities or substantially similar activities as described in Section I.A above. The specific activities excluded from the scope of the Proposed Rule were: (1) the Enterprises' AUS (Fannie Mae's Desktop Underwriter and Freddie Mac's Loan Product Advisor) and upgrades to the technology, operating system or software to operate an AUS; and (2) any modifications to mortgage terms and conditions or underwriting criteria relating to mortgages that are purchased or guaranteed by an Enterprise but that do not alter the nature of the underlying transaction as residential mortgage financing. The Proposed Rule also made explicit that business practices, transactions, or services performed or conducted solely to facilitate the administration of an Enterprise's internal affairs would be excluded as well. FHFA requested comment on how the exclusion for the AUS should apply to existing technology systems that are related but independent from the AUS, as well as to future technology systems, and whether the exclusions overall should be narrowed or expanded. Comments and questions related to the exclusions for substantially similar activities are addressed in a separate discussion below under the heading ''*Exclusions for Substantially Similar Activities.*''

In responding to the questions about the AUS exclusion and whether the exclusions overall should be expanded, one commenter was supportive of the proposed exclusions, believing them to be appropriate and consistent with the ''need for a rigorous review process that is not unduly time-consuming or stifling.'' Another commenter stated that the exclusion for activities involving the AUS should be narrowed and apply only to the capabilities of the AUS as of the effective date of the final rule. The commenter further argued that ''any new benefit, protection, right, relief, or change to the origination process—as well as activities traditionally associated with the primary mortgage market—should be considered new activities and outside the scope of the proposed exclusion.'' However, several commenters recommended that the exclusions be expanded to include technology systems that are related but independent from an AUS, such as the models and applications that assist an AUS in assessing the risk of a mortgage. One Enterprise asserted that an AUS is not a single technology system but is a collection of interrelated and integrated technology systems that embody the mortgage terms and conditions or underwriting criteria that are published in the Enterprises' respective selling and servicing guides, and therefore should be excluded, as was intended by the statute. The commenters who favored expanding the exclusion believe that subjecting these technology systems to the requirements of this final rule could unduly delay updates that incorporate new types of data or resources, potentially rendering the AUS obsolete over time because the market is moving or shifting faster than an Enterprise can update it through the new activity or new product process, and consequently exposing the Enterprise to increased risk. Two commenters and the Enterprises requested that the exclusions be expanded to name the actual integrated or interrelated technologies, such as Collateral Underwriter and Loan Collateral Advisor, among others. One commenter also suggested that technology innovations that merely enhance ease of access to housing data should also be excluded from the requirements of the final rule.

FHFA has carefully considered the commenters' suggestions for expanding the exclusion related to the AUS and believes it should remain as proposed. In retaining the exclusion as proposed, FHFA is striking a balance between excluding an activity that is part of an Enterprise's core business from prior notice requirements and including an activity that introduces new technology to the mortgage industry that may serve a primary market function. However, FHFA recognizes that some technologies perform functions similar to the AUS because they assist in applying the Enterprise's underwriting criteria and assessing the credit risk of the mortgage and that other technologies mirror the mortgage terms and conditions and underwriting criteria that are reflected in an Enterprise's selling and servicing guide. As a result, FHFA is revising the exclusion for substantially similar activities to include the technologies (other than the AUS) that apply underwriting criteria or mortgage terms and conditions to residential mortgages purchased or guaranteed by the Enterprises so that changes to systems such as Fannie Mae's Collateral Underwriter or Loan Delivery and Freddie Mac's Loan Collateral Advisor or Loan Selling Advisor do not require a notice of new activity. By revising the exclusions for substantially similar activities rather than the exclusions for an Enterprise AUS, FHFA achieves the balance it is seeking. In contrast to activities that fall under the AUS exclusion, an Enterprise must submit advance notice to FHFA before engaging in a substantially similar activity (notice of substantially similar activity). By reviewing a notice of substantially similar activity, the Agency can assess technological enhancements to ensure that they are substantially similar to the AUS or mortgage terms and conditions or underwriting criteria and are not a new activity or a new product.

As discussed previously, some commenters feared that the final rule could capture a large volume of routine activities, including revisions and updates to the Enterprises' internal risk management policies and selling and servicing guides. Conversely, another commenter felt that the public and FHFA should have the opportunity to assess potential changes to an Enterprise's underwriting criteria that would materially impact its credit box or consumer access to credit because the Enterprises ''essentially set the rules for the market.'' Commenters were also concerned that the underwriting and servicing policy changes put in place in response to the COVID–19 pandemic could have been treated as new activities under the Proposed Rule even though the changes did not result in a new product offering to the market. In a related comment, both Enterprises mentioned the significant number of lender letters and bulletins issued that addressed housing issues related to the pandemic, which kept borrowers and renters in their homes and made closings possible under social distancing requirements and shutdowns. Other commenters mentioned new loss mitigation activities

made available during the pandemic that should be explicitly excluded, such as the introduction of the Enterprises' new home retention repayment option that allows borrowers to defer unpaid mortgage payments and turn them into a noninterest-bearing balance due when the mortgage is paid off.

FHFA disagrees that routine activities, updates to the Enterprises' respective selling and servicing guides, or changes to underwriting criteria or mortgage terms and conditions are captured or should be captured under the final rule. In reviewing the comments, FHFA noted that many commenters did not seem to understand the scope of the exclusions, which, in keeping with the Act, are designed to exclude changes to mortgage terms and conditions or underwriting criteria relating to residential mortgages purchased or guaranteed by an Enterprise, such as an Enterprise's core activities involving its Single-Family and Multifamily business lines. For example, changes to an Enterprise's underwriting criteria or servicing and loss mitigation policies in response to the COVID–19 pandemic would not require an Enterprise to submit a notice of new activity to FHFA. However, several commenters seemed to believe that such changes, though specifically excluded by the Act, could and would be considered a new activity and require the Enterprise to submit a notice of new activity. FHFA believes the Act and the Proposed Rule clearly exclude activities that involve any modification to the mortgage terms and conditions or underwriting criteria for residential mortgage financing, such as those activities that resulted in temporary loss mitigation policies or underwriting flexibilities or restrictions in response to the pandemic. However, given that commenters had difficulty understanding the exclusions, FHFA is making changes to enhance clarity but retain the scope of the exclusions as proposed.

The Enterprises requested that the exclusions in the final rule be expanded to exclude activities under the Duty to Serve Regulation (12 CFR part 1282, subpart C). The Enterprises argued that those activities have already undergone a review by FHFA and were made available for public notice and comment, and therefore it would be a duplicative regulatory burden to make them subject to the final rule. The Enterprises also requested that the exclusion for any Enterprise business practice performed solely to facilitate the administration of an Enterprise's internal affairs be revised to make clear that the activities performed to mitigate their risk on mortgages that they purchase or guarantee are also excluded from the definition of a new activity.

FHFA is not adopting the Enterprises' requested changes to the exclusions in the final rule. An FHFA non-objection to an Enterprise's Duty to Serve plan—or an Equitable Housing Finance Plan, for that matter—applies only to the plan itself and not to the underlying activities. Therefore, it is not a duplicative regulatory burden but rather completely appropriate for such activities to be subject to the final rule if they meet one or more of the new activity criteria. Regarding the exclusion for business practices internal to the Enterprises, FHFA is not revising this exclusion because, as proposed, the exclusion already captures those risk mitigation activities that are internal to an Enterprise such as those mentioned by Freddie Mac in its comment letter (''establishing internal controls, updating obsolete systems and technologies, and improving efficiencies related to analyzing, processing, and documenting internal information''). However, if an Enterprise's risk mitigation activities are ultimately provided to the market in the form of an offering or service, they are no longer exclusively internal to the Enterprise and will be subject to the final rule if the activity meets one or more of the new activity criteria and is otherwise not excluded.

Exclusions for Substantially Similar Activities. As mentioned previously, FHFA proposed an exclusion for substantially similar activities as described in Section I.A. above. Several commenters found this exclusion confusing, with one stating that the Proposed Rule ''provides no clarity or definition as to what 'substantially similar' means for purposes of [the] exclusion.'' Another commenter recommended the removal of the provision in the final rule that stated that if an activity met one or more of the new activity criteria, it could not be considered substantially similar. A few commenters requested that the final rule clarify that the exclusion for an activity that is substantially similar to an approved new product is available to ''either'' Enterprise and not only to the Enterprise that did not obtain the original new product approval. Lastly, one Enterprise suggested that existing and future technology systems that are integral to an Enterprise's mortgage terms, conditions, and underwriting and have functions similar to the AUS could be considered ''substantially similar'' to the AUS system or to modifications to mortgage terms, conditions and underwriting criteria.

In response to these comments, FHFA is changing this section in the final rule to make it clear that this exclusion applies to ''either'' Enterprise. FHFA is also revising the final rule to adjust and clarify the scope of the exclusion in two principal ways. First, the final rule distinguishes the criteria used for determining whether an activity is substantially similar to activities that are otherwise excluded from the review and approval requirements under the Safety and Soundness Act (*i.e.,* changes to the AUS, mortgage terms and conditions, and underwriting criteria) from the criteria used for determining whether an activity is substantially similar to a new product that an Enterprise is authorized to offer to the market. The criteria for determining whether an activity is substantially similar to a new product are more rigorous than for determining whether an activity is substantially similar to an excluded activity. For example, activities like modifying the Enterprises' loan delivery systems or other technology systems to apply updated Qualified Mortgage criteria are not likely to merit public notice and comment because—like updates to the statutorily excluded AUS—they tend to be routine activities. However, under the Proposed Rule, this type of update to a technology system would require a notice of new activity. Similarly, simple changes to the risk scores provided by Collateral Underwriter or Loan Collateral Advisor may not satisfy the criteria for substantially similar and could require a notice of new activity each time a modification is made. Treating these types of modifications as new activities would be unduly burdensome on the Agency and on the Enterprises. To mitigate this burden, FHFA is revising the final rule so that the Director may determine that any technology that applies mortgage terms and conditions or underwriting criteria relating to residential mortgages that are purchased or guaranteed by an Enterprise or any modifications to those technologies (*e.g.,* modifications to Collateral Underwriter and Loan Collateral Advisor) are substantially similar to the statutorily excluded AUS, mortgage terms and conditions, or underwriting criteria.

Second, with respect to activities that are substantially similar to new products, FHFA recognizes that describing what are *not* substantially similar activities for purposes of the exclusion is potentially confusing and is revising this section to affirmatively describe what *are* substantially similar activities. Additionally, FHFA is

slightly expanding the scope of the exclusion in the final rule in a manner that is consistent with the goal of screening to confirm that the activity is not a new activity. For example, where the Proposed Rule provided that an activity would not be substantially similar to an approved new product if the activity required a new resource, type of data, policy, process, or infrastructure, the final rule provides that the Director may determine that an activity is substantially similar to an approved new product if the activity requires the same *or similar* resource, type of data, policy, process, or infrastructure as the approved new product. These changes should provide the clarity that commenters and the Enterprises are seeking for this exclusion.

Treatment of Pilots. As part of the new activity description and exclusions, FHFA proposed to include activities that are pilots or that result from a pilot as among the criteria that would identify a new activity. Under the Proposed Rule, a pilot was defined as an activity that had a defined term and scope for the purposes of understanding the viability of a new offering, and FHFA recognized that pilots are referred to in different ways, such as a testing initiative, test and learn, or temporary authorization.

FHFA received a wide range of comments about including pilots as one of the criteria for identifying a new activity. Several commenters supported their explicit inclusion in the scope of a new activity to help minimize ''pilot creep.'' Some commenters suggested that the final rule should have formal constraints on the duration and volume for pilots that would require the Enterprise to submit a new notice when the pilot reached those limits. Other commenters and the Enterprises took the opposite position and stated that including pilots in the scope of a new activity is too broad and would stifle innovation. One commenter argued that the word ''pilot'' should be removed from the definition of a new activity ''. . . as the word has never been clearly defined or consistently applied throughout the industry.'' The same commenter also suggested that pilots should be excluded from the new activity description. Finally, several commenters stressed that there is a lack of transparency and inclusivity for pilots, giving some market participants an advantage over others, which they believe FHFA should address through the final rule.

FHFA disagrees with the commenters who suggested that pilots should be excluded from the scope of a new activity. As noted by several other commenters, a pilot is how an Enterprise typically determines the viability of a future offering. In general, Enterprise products and activities have significant effects on the market and market participants. Regardless of the size of a pilot, it could have a significant effect on the public interest. Therefore, it is critical for FHFA to review pilots as new activities to determine whether they are indeed new products that merit public notice and comment.

FHFA agrees with commenters that there should be process requirements for reviewing pilots beyond what was proposed, and has added language to the final rule that requires an Enterprise to submit a notice of new activity both when a pilot is initiated and when modifications to the volume and duration of the pilot are made after it commences. FHFA recognizes that pilots can extend for lengthy periods of time or change form as a natural consequence of conducting exploratory business, which is why the notice of new activity, as proposed, required the Enterprise to establish the parameters, such as the duration and volume of the pilot. FHFA also believes that requiring a subsequent notice of new activity for a pilot when there are changes to the duration and volume would help manage ''pilot creep'' and facilitate a determination of whether the activity is a new product that merits public notice and comment.

While several commenters recommended that the final rule should require an Enterprise to be inclusive when selecting participants for a pilot, FHFA believes that such requirements are not within the scope of this final rule and are already in place in the broader regulatory framework governing an Enterprise's activities. FHFA's Minority and Women Inclusion and Diversity Regulation at 12 CFR 1223.2 requires the Enterprises ''to promote diversity and ensure . . . the inclusion and utilization of minorities, women, individuals with disabilities, and minority—, women—, and disabled-owned businesses at all levels, in management and employment, in all business and activities, and in all contracts for services of any kind.'' That Regulation governs not just an Enterprise's new activities as described in the final rule, but *all* Enterprise activities.

D. Public Interest Factors

FHFA proposed eight factors that the Director may consider when determining whether a new product is in the public interest. These are the same factors on which the Director would seek public comment to inform the decision as to whether to approve or disapprove a new product. The public interest factors fall into three broad categories: (1) the impact of the new product on the Enterprise's public mission; (2) the impact of the new product in terms of risk to the mortgage finance or financial system; and (3) the impact of the new product on the competitiveness of the market. In addition, the Director retained the discretion to seek public comment on and consider any other public interest factors determined to be appropriate to consider during the approval process.

More than half of the commenters, including both Enterprises, provided comments on factors that FHFA should or should not include in the consideration of whether a new product is in the public interest. Several commenters suggested additional factors that, if incorporated, would inform the degree to which the new product would promote competition in the marketplace, or to the contrary would result in less competition. One commenter suggested that FHFA include a factor focused on the degree to which a new product would enable the Enterprise to ''compete against market participants that they effectively regulate.'' Several commenters requested that the public interest factors make explicit reference to the degree to which the new product would have a disruptive or inequitable impact on different types or sizes of lenders. While most commenters sought the inclusion of factors that would contribute to an evaluation of whether the new product would harm competition, other commenters (including the Enterprises) viewed the public interest factors as overly protective of competition, with one Enterprise arguing that the public interest analysis ''should focus on protecting competition, not competitors.'' These commenters requested the removal of the public interest factor that prompts an evaluation of the degree to which the new product is being or could be supplied by other market participants.

FHFA has considered the feedback from commenters and has determined that the public interest factors, as proposed, enable FHFA to conduct a holistic evaluation of the impact of a new product on competition. There are numerous ways that a new product could help or hinder competition. The Proposed Rule specifically enumerated two such factors for evaluation—the degree to which the new product would overcome natural market barriers or inefficiencies and the degree to which the new product could be supplied by

other market participants. These factors are in addition to a catchall provision that prompts the evaluation of the degree to which the new product would promote competition in the marketplace, or to the contrary would result in less competition. Together, these factors will enable FHFA to seek public comment and form a holistic and balanced view of the impact of the new product on competition.

In addition to the comments related to competition, commenters suggested a variety of public interest factors that should be included in FHFA's evaluation. For example, one commenter wanted the public interest factors to prompt an evaluation of the impact of the new product on housing costs for low- and moderate-income borrowers, while another commenter indicated that the public interest factors should include the degree to which the new product would aid in addressing natural disasters. FHFA has considered these comments and determined that the concerns are adequately addressed by specific public interest factors (such as the degree to which the new product serves underserved markets and housing goals) or through the discretion retained by the Director to seek public comment and evaluate any other appropriate factor. The discretion retained by the Director provides an avenue to address considerations that may not be relevant for all new products at all times, such as the degree to which the new product would aid in addressing natural disasters.

E. Enterprise Confidentiality

Confidential Treatment of Enterprise Submissions; Public notices. FHFA did not propose explicit protections for confidential information provided to FHFA by an Enterprise in connection with a notice of new activity. Several commenters, including both Enterprises, recommended that the final rule include such protections. Reasons cited included the need to avoid discouraging innovation, the need to protect an Enterprise's ability to comply with contractual obligations to third parties, and the need to protect an Enterprise from competitive harm. One commenter noted that ''this is one of the trickiest elements of the entire Proposed Rule,'' acknowledging that it is ''challenging to provide sufficient details to elicit meaningful public commentary without requiring an Enterprise to disclose key business details'' which might ''discourage future innovations.'' The Enterprises also commented that the treatment of confidential information in the Proposed Rule was inconsistent with FHFA's treatment of confidential information in other contexts, such as its rules on application of the Freedom of Information Act (FOIA) (5 U.S.C. 552; 12 CFR part 1202) and Enterprise Duty to Serve (12 CFR 1282.32(g)(2)). The Enterprises noted that, at a minimum, FHFA should provide the same protections for information contained in a new activity or new product submission that FHFA provides for many other communications between FHFA and its regulated entities.

FHFA has considered the comments and determined that no changes to the treatment of confidential information are warranted for the final rule. FHFA's treatment of confidential information in the final rule is appropriate to the context and in line with the intent of the underlying statute.

An Enterprise may request that information provided to FHFA in any context, including as part of a new activity or new product submission, be afforded protection from public disclosure under FOIA and FHFA's implementing regulation, 12 CFR part 1202. The fact that the final rule does not mention FOIA does not mean protections provided to an Enterprise under FOIA are unavailable. However, FOIA protections are triggered only when a member of the public requests that FHFA disclose information that an Enterprise has requested be kept confidential. As a general matter, FOIA does not limit or preclude FHFA from disclosing confidential, proprietary, or other non-public information at its own initiative. FHFA's independent decision to disclose non-public information in connection with the publication of a notice soliciting public comments on a proposed Enterprise new product is governed by FHFA's Availability of Non-public Information Regulation (12 CFR part 1214).

FHFA's Availability of Non-public Information Regulation grants the Director broad discretion to authorize the disclosure of non-public information. The Director's discretion is informed by statutory duties under the Safety and Soundness Act, including duties to ensure that the Enterprises operate in a safe and sound manner, that the operations and activities of the Enterprises foster liquid, efficient, competitive, and resilient housing finance markets, and that the activities of the Enterprises and the manner in which they operate are consistent with the public interest. The Director's exercise of discretion is also subject to privacy and other laws and regulations that may limit certain disclosures. Within this complex framework, FHFA must always be mindful of the need to protect sensitive information from public disclosure. Where the Director exercises discretion to authorize disclosure of non-public information, the Director, in view of the statutory and regulatory framework that governs such disclosure, balances the need for disclosure against other statutory responsibilities that may be facilitated by protecting sensitive information.

Striking the appropriate balance is context specific. Where the statutory or regulatory framework requires or encourages FHFA to publish the regulatory submissions prepared by an Enterprise or a Federal Home Loan Bank, FHFA's practice has been to omit confidential information from those publications (*e.g.,* Duty to Serve Underserved Markets Plans). In some cases—for example, under the Enterprise Resolution Planning Regulation (12 CFR part 1242) and the Federal Home Loan Bank Housing Goals Regulation (12 CFR part 1281)—this practice is facilitated by requesting that the regulated entity segregate confidential and non-confidential information into separate documents so that the non-confidential submissions can be published in their entirety.

The final rule strikes the appropriate balance between the need for disclosure and protecting sensitive information. In recognition of the fact that a substantial portion of an Enterprise's new product submission is likely to contain information that an Enterprise would prefer to remain confidential, FHFA does not expect to publish the submission or supporting documentation in whole. Instead, FHFA will review the submissions and, based on the information it contains, prepare a notice that provides the public with enough information to comment on the extent to which the proposed new product would serve the public interest. The public notice may include information that an Enterprise would prefer to be kept confidential. However, this approach is consistent with the statutory intent that FHFA disclose information to the public about a potential Enterprise new product prior to it being offered to the market. But for the statute, this information customarily would not be made public. The Director would make any such disclosures in view of the regulatory framework that governs FHFA's disclosure of non-public information, the statutory intent underpinning the final rule, and the Director's other statutory duties.

F. FHFA Transparency and Reporting

While some commenters expressed the need to protect the confidentiality of Enterprise submissions, most commenters sought greater transparency

into Enterprise new activities. Commenters expressed various perspectives on how transparency could be enhanced. Several commenters suggested that FHFA should report on Enterprise new activities on a monthly, quarterly, or annual basis. Commenters' suggestions on the content of that reporting can be grouped into two categories—transparency about the new activities themselves and transparency into FHFA's decision-making.

With respect to the new activities, one commenter noted that the reporting should identify the Enterprise that submitted the notice and describe the basic parameters of a proposed activity, but not be so specific as to disclose operational details that might reveal confidential aspects of the work under development ''that are not ready for public consumption.'' In contrast, another commenter seemed to suggest that reporting on a new activity should be ongoing and include a list of all new activities and the market participants involved. Along the same lines, another commenter recommended that FHFA conduct an *ex post* evaluation of each new product after six months and that the resulting analysis should be made publicly available.

Several commenters also requested that FHFA publish a summary of its determinations on Enterprise new activity submissions. One commenter noted that this disclosure could provide some insight into Enterprise reaction to market trends and would give stakeholders a more informed ''view of the dedication of Enterprise time and resources to innovation and a clearer picture of the types of activities that FHFA will and will not deem to be permissible for an Enterprise[ ] to pursue.'' Another commenter remarked that in the absence of insight into why a proposed product was denied approval, the Enterprises and other market participants might refrain from investing human and financial resources into developing Enterprise new products.

FHFA agrees with the commenters suggestions that the final rule should have a provision that requires Agency reporting on the Enterprises' new activity and new product submissions and FHFA's decisions. FHFA anticipates leveraging existing reports, such as the Annual Report to Congress or annual Performance and Accountability Report, to include a section that identifies new activity and new product submissions by Enterprise, describes the basic parameters of proposed activities or products, and summarizes FHFA's new product determinations, approvals, and disapprovals and the basis for those decisions. Reporting under this new provision would omit confidential and proprietary information not already published in connection with the public notice for a new product since the report is for information only and the public would not be asked to comment.

III. Section-by-Section Analysis of the Final Rule

A. Purpose and Authority; Definitions—§§ 1253.1 and 1253.2

Section 1253.1 of the final rule sets out the purpose and authority of the rule, which is to implement the Director's authority under section 1321 of the Safety and Soundness Act to review and approve new Enterprise products before they are offered to the market. Section 1253.2 of the final rule defines key terms used in the regulation. Of particular significance, the final rule defines ''activity'' as a business line, business practice, offering, or service, including a guarantee, a financial instrument, consulting or marketing, that the Enterprise provides to the market either on a standalone basis or as part of a business line, business practice, offering, or service. While this definition was implied by the Proposed Rule, it was not stated explicitly. In line with the Proposed Rule, § 1253.2 of the final rule also defines ''pilot'' as an activity that has a limited term and scope for purposes of evaluating the viability of the activity, regardless of the name assigned to the activity. The word ''limited'' has been added to enhance clarity. ''New activity'' and ''new product'' have the meanings assigned to them under §§ 1253.3 and 1253.4 of the final rule, respectively.

B. New Activity Description and Exclusions—§ 1253.3

New Activities. Section 1253.3 of the final rule describes the criteria for identifying a new activity and describes the activities which are excluded from the review and approval requirements by statute. Because the final rule includes an explicit definition for ''activity,'' the structure of this section has changed from the Proposed Rule to reflect that addition and to improve clarity. A threshold criterion for distinguishing an ongoing activity from a new activity is timing. Under § 1253.3(a)(1) of the final rule, an activity is a ''new activity'' if it is not engaged in by the Enterprise on or before the effective date of the regulation. However, § 1253.3(a)(2) of the final rule provides that if an Enterprise does engage in an activity on or before the effective date of the regulation, but the Enterprise enhances, alters, or modifies the activity after the effective date of the regulation so as to: (1) require a new resource, type of data, policy (or modification to an existing policy), process, or infrastructure; (2) expand the scope or increase the level of credit risk, market risk, or operational risk to the Enterprise; or (3) involve a new category of borrower, investor, counterparty, or collateral, then the resultant activity would be considered a ''new activity.'' This approach simplifies the criteria for determining whether an activity is a new activity that was presented in the Proposed Rule without altering the scope of activities captured.

Section 1253.3(a)(3) and (4) of the final rule include two additional categories of new activities that are intended to comprehensively capture an Enterprise's activities related to pilots. Section 1253.3(a)(3) of the final rule classifies as a new activity: (1) any pilot engaged in by an Enterprise after the effective date of the regulation; and (2) any modification to the volume or duration of a pilot that occurs after the effective date of the regulation, regardless of whether the Enterprise initially engaged in the pilot before or after the effective date of the regulation. Section 1253.3(a)(4) of the final rule captures the transition from a pilot into an ongoing activity, regardless of whether the Enterprise initially engaged in the pilot before or after the effective date of the regulation. While an Enterprise's activities related to pilots are likely to also fall within the scope of § 1253.3(a)(1) or (2) of the final rule, including targeted provisions on pilots in the final rule emphasizes FHFA's commitment to closely scrutinize them. For this reason, the final rule expands the scope of pilots captured as new activities to include modifications to the volume or duration of a pilot. Unless a pilot or an activity resulting from a pilot falls into one of the exclusions set forth at § 1253.3(b) of the final rule, an Enterprise must submit a notice of new activity or a request for prior approval as a new product, as appropriate.

The final rule does not reflect one element of the new activity description from the Proposed Rule. Section 1253.3(a)(3)(iv) of the Proposed Rule provided that an activity could be a new activity if it would substantially impact the mortgage finance system, the Enterprise's safety and soundness, compliance with the Enterprise's authorizing statute, or the public interest. On further reflection, FHFA has determined that it would be unreasonable to hold the Enterprises to account for failing to file a notice of new

activity based on the subjective determinations required by this provision.

Exclusions. As noted above, the following activities are excluded from the review and approval requirements under the Safety and Soundness Act: (1) the Enterprises' AUS, and any upgrades to the technology, operating system, or software to operate the underwriting system; (2) any modifications to mortgage terms and conditions or underwriting criteria relating to mortgages that are purchased or guaranteed by an Enterprise but that do not alter the nature of the underlying transaction as residential mortgage financing; and (3) substantially similar activities, as defined in Section I.A above. *See* section 1321(e) of the Safety and Soundness Act (12 U.S.C. 4541(e)). Section 1253.3(b) of the final rule incorporates these statutory exclusions and makes clear that activities conducted to facilitate the administration of an Enterprise's internal affairs but which are not provided to the market are also excluded from the review and approval requirements of section 1321 of the Safety and Soundness Act.

The final rule clarifies the scope of the exclusions related to the AUS and mortgage terms and conditions or underwriting criteria but does not modify the scope of the exclusions, which remain as proposed. To further enhance clarity of the exclusions, the final rule interprets ''upgrades'' to an Enterprises' AUS and ''modifications'' to mortgage terms and conditions or underwriting criteria in a way that ensures that these types of changes are not inadvertently captured by the new activity description. Accordingly, a new activity does not include any enhancement, alteration, or modification to the technology, operating system, or software to operate the AUS or to mortgage terms and conditions or underwriting criteria that does not alter the nature of the underlying transaction as residential mortgage financing is excluded from the new activity description, even if that change: (1) requires a new resource, type of data, policy (or modification to an existing policy), process, or infrastructure; (2) expands the scope or increases the level of credit risk, market risk, or operational risk to the Enterprise; or (3) involves a new category of borrower, investor, counterparty, or collateral.

The final rule also revises the description of substantially similar activities in a manner that makes the exclusion easier to understand and more closely aligned with the statute, including with respect to the treatment of technology systems that apply or mirror the Enterprises' mortgage terms and conditions or underwriting criteria. A more detailed discussion of these revisions is found in Section G below.

C. New Product Determination—§ 1253.4

Under § 1253.4(a) of the final rule, a new activity is a new product if the Director determines that the new activity merits public notice and comment about whether the proposed activity serves the public interest. This reflects a simplified approach from the Proposed Rule under which the Director would make the determination whether the new activity is a new product based on whether the new activity merits public notice and comment on three criteria: (1) compliance with specific provisions of the Enterprises' respective authorizing statutes; (2) the safety and soundness of the Enterprise or the mortgage finance system; and (3) the public interest.

The revisions to the new product determination criteria have been made for two reasons. First, FHFA is unlikely to seek public comment on redundant topics. FHFA proposed eight factors that the Director may consider when determining whether a new product is in the public interest. These are the same factors on which the Director would seek public comment to inform the decision as to whether approval of a new product would be in the public interest. To a large extent, the determination criteria in § 1253.4(a) of the Proposed Rule overlapped with the public interest factors in proposed § 1253.4(b). For example, one of the public interest factors examines the degree to which the proposed new product would advance the purposes of the Enterprise under its authorizing statute, which is similar to the determination criterion in § 1253.4(a) of the Proposed Rule about the new activity's compliance with specific provisions of the Enterprise's authorizing statute. Another public interest factor examines the degree to which the proposed new product might raise or mitigate risks to the mortgage finance or financial system, which is similar to the criterion in § 1253.4(a) of the Proposed Rule about the safety and soundness of the Enterprise or the mortgage finance system. While two of determination criteria have been deleted, the public interest factors remain unchanged from the Proposed Rule, and the Director retains the discretion to include other factors deemed appropriate to consider during the approval process. Second, one Enterprise raised a concern that seeking public input on the determination criteria in the Proposed Rule would likely require the public disclosure of confidential or privileged information. FHFA believes that it can adequately assess compliance with specific provisions of the Enterprises' respective authorizing statutes, as well as the safety and soundness of the Enterprise or the mortgage finance system, without seeking public input beyond what would be sought through the public interest factors.

D. Notice of New Activity—§ 1253.5

Section 1253.5 of the final rule establishes the procedural framework for Enterprise submission and FHFA review of a notice of new activity. Before commencing any new activity, an Enterprise must submit to FHFA a written notice, the content of which is described in § 1253.9 of the final rule. Consistent with the Proposed Rule, an Enterprise includes any of its affiliates (*see* 12 U.S.C. 4502; 12 CFR 1201.1) and if the new activity is to be offered by an affiliate, either the Enterprise or its affiliate may submit the required notice. In contrast to the Proposed Rule and in response to comments, the final rule explicitly states that an Enterprise may request prior consultation with FHFA about whether a notice of new activity is required. Circumstances which may merit a consultation could include when the Enterprise is uncertain about whether a notice of new activity is required.

A notice of new activity will not be considered complete and received for processing until the information required by § 1253.9 of the final rule has been submitted, including any follow-up information required by FHFA. Section 1253.5(c) of the final rule provides that nothing in the rule limits or restricts FHFA from reviewing the notice of new activity under any other applicable regulation or statute, as part of FHFA's authority to review for safety and soundness and for consistency with an Enterprise's statutory mission. For example, if a proposed new activity necessitated a review for compliance with the Uniform Mortgage-Backed Securities Regulation (12 CFR part 1248), FHFA's receipt of information necessary for that review may be part of FHFA's determination that the notice of new activity is complete and has been received.

The final rule provides that an Enterprise may not commence a new activity unless the Director makes a written determination that the new activity is not a new product within 15 days, or the 15 days pass and no

determination is made. If the Director determines that the new activity is a new product, the Enterprise must elect to submit a request for prior approval of a new product and await approval of the new product under § 1253.6 of the final rule or it must discontinue its plan to offer the new product to the market. Providing this optionality for the Enterprises reflects a change from the Proposed Rule in response to the Enterprises' request to be permitted to decide whether to continue to pursue the offering following a new product determination. If FHFA issues a determination that the new activity is not a new product, or the 15 days pass without any determination, the Enterprise may begin the new activity, subject to such terms, conditions, or limitations as the Director may establish.

E. Request for Prior Approval of a New Product; Public Notice; Standards for Approval—§ 1253.6

The final rule introduces the concept of a request for prior approval of a new product that is distinct from a notice of new activity. This change responds to commenters' concerns that the Proposed Rule did not provide this distinction and accommodates the changes made to § 1253.5 of the final rule that permit an Enterprise to decide whether it still wants to pursue an offering following a new product determination. Section 1253.6 of the final rule establishes the procedural framework for Enterprise submission and FHFA review of a request for prior approval of a new product. An Enterprise must submit a request for prior approval of a new product to FHFA before offering a new product to the market. However, since a determination by the Director under § 1253.4 of the final rule is required for a new activity to be classified as a new product, an Enterprise may only submit a request for prior approval of a new product if the Director has made such a determination. The Director may make a determination that a new activity is a new product at the conclusion of the Agency's review of a new activity or at the conclusion of an Enterprise's voluntary consultation with FHFA.

A request for prior approval of a new product will not be considered complete and received for processing until the information required by § 1253.9 of the final rule has been submitted, including any additional information requested by FHFA. In response to commenters' concerns that FHFA has an unlimited amount of time to prepare a public notice, the final rule makes clear that once FHFA makes the determination that the request for prior approval is ''received,'' FHFA will publish a public notice soliciting comments on the proposed new product without delay. FHFA will include in that public notice enough information from the request for prior approval of a new product to sufficiently describe the new product so that the public can provide meaningful comment. The final rule clarifies that the public notice will be published on FHFA's website and in the **Federal Register**. In response to public comments that requested FHFA to maximize time for public comment, the statutory 30-day comment period will commence on the date that the notice is published in the **Federal Register**, which is expected to be later than the date on which the notice is published on FHFA's website. The public notice will provide instructions for submission of public comments. As is the practice with other requests for information and proposed rules, comments submitted by the public on a new product will be made public and posted on FHFA's website.

In determining whether to approve a new product, the Director will consider all public comments received by the closing date of the comment period. The final rule incorporates the Safety and Soundness Act's approval requirements by providing that the Director may approve the new product if the Director determines that the new product: (1) in the case of Fannie Mae, is authorized under 12 U.S.C. 1717(b)(2), (3), (4), or (5) or 12 U.S.C. 1719; or (2) in the case of Freddie Mac, is authorized under 12 U.S.C. 1454(a)(1), (4), or (5); (3) is in the public interest; and (4) is consistent with the safety and soundness of the Enterprise or the mortgage finance system.

In accordance with the statutory timelines, the Director will make a determination on the new product no later than 30 days after the close of the public comment period. If no determination is made within that timeframe, the Enterprise may offer the new product. As with a new activity, a new product may be subject to any terms, conditions, or limitations as the Director may establish. Also, as with a new activity, the Director may review for safety and soundness or consistency with the Enterprise's statutory mission at any time; exercise of that authority is not constrained by any time limit provided for in the Act or reflected in the final rule.

F. Temporary Approval of a New Product—§ 1253.7

Section 1253.7 of the final rule incorporates the statutory provision empowering the Director to make a new product temporarily available to the market without first seeking public comment. Section 1321(c) of the Safety and Soundness Act (12 U.S.C. 4541(c)) authorizes the Director to grant temporary approval of a new product if the Director finds ''that the existence of exigent circumstances makes [the delay associated with seeking public comment] contrary to the public interest.'' Section 1321(c)(4)(C) of the Act (12 U.S.C. 4541(c)(4)(C)). Under the final rule, an Enterprise may request temporary approval of a new product, or FHFA may act on its own initiative. The Director may impose terms, conditions, or limitations on the temporary approval, and upon the granting of a temporary approval for a new product, FHFA will begin the process for permanent decision on the proposed new product in accordance with § 1253.6 of the final rule, including issuing a notice for public comment without delay. This section remains unchanged from the Proposed Rule, except for conforming paragraph numbering.

G. Substantially Similar Activities—§ 1253.8

As noted above, ''substantially similar activities'' are excluded from the review and approval requirements of the Safety and Soundness Act. Section 1253.8 of the final rule establishes the procedural framework for an Enterprise to offer a substantially similar activity. An Enterprise must provide written notice to FHFA of its intent to offer the substantially similar activity at least 15 days prior to offering the activity to the market. In contrast to the other statutory exclusions which do not require notice (*e.g.,* the AUS and enhancements, alterations, or modifications to mortgage terms and conditions or underwriting criteria), advance notice to FHFA is required for any substantially similar activity so that FHFA may exercise its regulatory and supervisory responsibilities to ensure that the activity qualifies for the exclusion.

The notice of substantially similar activity required under § 1253.8 of the final rule is distinct from a notice of new activity. Section 1253.8(d) of the final rule provides that a notice of substantially similar activity must include the name and a complete and specific description of the activity, as well as an explanation of why the Enterprise believes the activity qualifies as a substantially similar activity under § 1253.8(b) of the final rule. However, if the Director determines that the activity is not a substantially similar activity, the Enterprise must submit a notice of new activity under § 1253.5 of the final

rule or a request for prior approval of a new product under § 1253.6 of the final rule and may not proceed with the activity until the requirements of those sections, as applicable, have been satisfied.

The final rule revises the description of substantially similar activities in a manner that makes the exclusion easier to understand and aligns more closely with the statute, including with respect to the treatment of technology systems that are related but independent of an Enterprise's AUS. The final rule distinguishes the criteria used for determining whether an activity is substantially similar to activities that are otherwise excluded from the review and approval requirements under the Safety and Soundness Act (*e.g.,* the AUS) from the criteria used for determining whether an activity is substantially similar to a new product that an Enterprise is authorized to offer to the market. The final rule also clarifies the criteria related to the latter category of substantially similar activities. Accordingly, under § 1253.8(b) of the final rule, the Director may determine that an activity is substantially similar to: (1) the AUS, including any enhancement, alteration, or modification to the technology, operating system, or software to operate the AUS; or (2) any enhancement, alteration, or modification to mortgage terms and conditions or underwriting criteria relating to residential mortgages that are purchased or guaranteed by an Enterprise if the activity is a technological implementation of mortgage terms and conditions or underwriting criteria relating to residential mortgages that are purchased or guaranteed by an Enterprise. Under § 1253.8(c) of the final rule, the Director may determine that an activity is substantially similar to a new product that the Director has approved for either Enterprise or that is permissible for either Enterprise to offer because the statutory timeframe lapsed without the Director rendering a decision on a request for prior approval of a new product, if the activity: (1) requires the same or a similar resource, type of data, policy, process, and infrastructure; (2) entails the same or similar levels of credit risk, market risk, and operational risk to the Enterprise; and (3) involves the same or a similar category of borrower, investor, counterparty, and collateral. In contrast, the Proposed Rule used a single set of negative criteria to identify which (if any) activities would qualify as substantially similar. The Proposed Rule also indicated that the exclusion for activities that were substantially similar to approved new products was available only to the Enterprise that did not receive approval for the original product, a result which is inconsistent with the provisions of the Act.

H. New Activity and New Product Submission Requirements—§ 1253.9

In response to comments regarding the burdensome submission process, § 1253.9 of the final rule introduces a two-step process for an Enterprise to submit information to FHFA with respect to a potential new product and makes minor adjustments to the required content. The scope of the information required for a notice of new activity is set out in § 1253.9(a) of the final rule. These streamlined information requirements include the five requirements from the Proposed Rule that are most critical to enable FHFA to assess the impact, risks, and benefits of a new activity and determine whether the new activity is a new product. If the Director determines that the new activity is a new product (following the review of a notice of new activity or following an Enterprise's voluntary consultation with FHFA), and the Enterprise elects to proceed with a request for prior approval of a new product, then the Enterprise must provide the additional information set out in § 1253.9(b) of the final rule. Those information requirements are substantially more detailed than what is required in connection with a notice of new activity, to ensure that FHFA can provide the public with sufficient information to review and meaningfully comment on the proposed new product and that the Director has the information required to inform any determination under the statutory standards for approval of a new product. The final rule removes one element of required content from the Proposed Rule—an Enterprise would not be required to indicate its view as to whether a new activity is a new product since the request for prior approval of a new product would only occur after the Director made such a determination.

I. Public Disclosure—§ 1253.10

Section 1253.10 of the final rule provides a mechanism for FHFA to enhance the transparency of its decision-making on new product determinations, approvals, and disapprovals. The provision commits FHFA to publish information related to the Director's determinations on new activity and new product submissions within a reasonable time period after the end of the calendar year during which the Enterprises filed such submissions. Any reporting by FHFA under this provision would not disclose confidential or proprietary information provided to FHFA by an Enterprise.

J. Preservation of Authority—§ 1253.11

The content of section 1253.11of the final rule is unchanged from § 1253.10(a) of the Proposed Rule, but has been reformatted in the final rule. Section 1253.11 of the final rule confirms that the Director's exercise of authority to review new Enterprise activities and products under section 1321 of the Safety and Soundness Act in no way restricts any other authority of the Director over new and existing Enterprise activities or products, including the authority of the Director to review new and existing activities or products for safety and soundness or consistency with the statutory mission of the Enterprise. *See* section 1321(f) of the Safety and Soundness Act (12 U.S.C. 4541(f)). Under this authority, for example, the Director could find that an ongoing activity should be subject to certain conditions or terms.

Section 1253.10 (b) of the Proposed Rule, which as proposed set forth the actions that FHFA may take if an Enterprise fails to comply with the provisions of the rule, has been deleted from the final rule. FHFA has determined that it would be redundant to restate authorities contained elsewhere in the applicable legal and regulatory framework.

IV. Regulatory Analyses

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. FHFA need not undertake such an analysis if the Agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)). FHFA has considered the impact of the final rule under the Regulatory Flexibility Act, and FHFA certifies that the final rule will not have a significant economic impact on a substantial number of small entities because the regulation only applies to Fannie Mae and Freddie Mac, which are not small entities for purposes of the Regulatory Flexibility Act.

B. Paperwork Reduction Act

The final rule does not contain any information collection requirement that requires the approval of the Office of

Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Therefore, FHFA has not submitted any information to OMB for Paperwork Reduction Act review.

C. Congressional Review Act

In accordance with the Congressional Review Act (5 U.S.C. 801 *et seq.*), FHFA has determined that this final rule is a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 12 CFR Part 1253

Government-sponsored enterprises, Mortgages, New activities, New products.

Authority and Issuance

■ For the reasons stated in the preamble, under the authority of 12 U.S.C. 4526 and 12 U.S.C. 4541, FHFA amends Chapter XII of Title 12 of the Code of Federal Regulations by revising part 1253 to read as follows:

PART 1253—PRIOR APPROVAL FOR ENTERPRISE PRODUCTS

Sec.

Authority: 12 U.S.C. 4511; 12 U.S.C. 4513; 12 U.S.C. 4526; 12 U.S.C. 4541.

§ 1253.1 Purpose and authority.

The purpose of this part is to establish policies and procedures implementing the prior approval authority for Enterprise products, in accordance with section 1321 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4541), as amended (Safety and Soundness Act).

§ 1253.2 Definitions.

For purposes of this part:

Activity means a business line, business practice, offering, or service, including a guarantee, a financial instrument, consulting or marketing, that the Enterprise provides to the market either on a standalone basis or as part of a business line, business practice, offering, or service.

Authorizing statute means the Federal National Mortgage Association Charter Act and the Federal Home Loan Mortgage Corporation Act, as applicable.

Credit risk is the potential that a borrower or counterparty will fail to meet its obligations in accordance with agreed terms. Credit risk includes the decline in measured quality of a credit exposure that might result in increased capital costs, provisioning expenses, or a reduction in economic return.

Days means calendar days.

Market risk means the risk that the market value, or estimated fair value if the market value is not available, of an Enterprise's portfolio will decline as a result of changes in interest rates, foreign exchange rates, or equity or commodity prices.

New activity has the meaning provided in § 1253.3.

New product has the meaning provided in § 1253.4.

Operational risk means the risk of loss resulting from inadequate or failed internal processes, people, or systems, or from external events, including all direct and indirect economic losses related to legal liability. Operational risk includes reputational risk, which is the potential for substantial negative publicity regarding an Enterprise's business practices.

Pilot means an activity that has a limited term and scope for purposes of evaluating the viability of the activity. A pilot may also be referred to as a testing initiative, test and learn, temporary authorization, or by other names.

§ 1253.3 New activity description and exclusions.

(a) A new activity is any of the following if not engaged in by the Enterprise on or before February 27, 2023:

(1) An activity;

(2) An enhancement, alteration, or modification to an activity that—

(i) Requires a new resource, type of data, policy, modification to an existing policy, process, or infrastructure;

(ii) Expands the scope or increases the level of credit risk, market risk, or operational risk to the Enterprise; or

(iii) Involves a new category of borrower, investor, counterparty, or collateral;

(3) A pilot or a modification to the volume or duration of a pilot, including a modification to a pilot that commenced before February 27, 2023; or

(4) An activity that results from a pilot (including from a pilot that commenced before February 27, 2023) or an enhancement, alteration, or modification (as described by paragraphs (a)(2)(i) through (iii) of this section) to an activity that results from a pilot (including from a pilot that commenced before February 27, 2023).

(b) A new activity excludes:

(1) An enhancement, alteration, or modification (as described by paragraphs (a)(2)(i) through (iii) of this section) to the technology, operating system, or software to operate the automated loan underwriting system of an Enterprise that was in existence as of July 30, 2008.

(2) An enhancement, alteration, or modification (as described by paragraphs (a)(2)(i) through (iii) of this section) to the mortgage terms and conditions or mortgage underwriting criteria relating to the mortgages that are purchased or guaranteed by an Enterprise, provided that such enhancement, alteration, or modification does not alter the underlying transaction so as to include services or financing, other than residential mortgage financing.

(3) Pursuant to the requirements of § 1253.8, any activity undertaken by an Enterprise that is substantially similar to—

(i) The automated loan underwriting system of an Enterprise that was in existence as of July 30, 2008, including or any enhancement, alteration, or modification to the technology, operating system, or software to operate the automated loan underwriting system;

(ii) Any enhancement, alteration, or modification to mortgage terms and conditions or mortgage underwriting criteria relating to the mortgages that are purchased or guaranteed by an Enterprise, provided that such activity does not alter the underlying transaction so as to include services or financing, other than residential mortgage financing; and

(iii) A new product that the Director has approved for either Enterprise under § 1253.6(a) through (f) or § 1253.7 or a new product that is otherwise available to either Enterprise under § 1253.6(h).

(4) Any Enterprise business practice, transaction, or conduct performed solely to facilitate the administration of an Enterprise's internal affairs.

§ 1253.4 New product determination.

(a) A new product is any new activity that the Director determines merits public notice and comment about whether it is in the public interest.

(b) The factors that the Director may consider when determining whether a new product is in the public interest are:

(1) The degree to which the new product might advance any of the purposes of the Enterprise under its authorizing statute;

(2) The degree to which the new product serves underserved markets and housing goals as set forth in sections 1332–1335 of the Safety and Soundness Act (12 U.S.C. 4562–4565);

(3) The degree to which the new product is being or could be supplied by other market participants;

(4) The degree to which the new product promotes competition in the marketplace or, to the contrary, would result in less competition;

(5) The degree to which the new product overcomes natural market barriers or inefficiencies;

(6) The degree to which the new product might raise or mitigate risks to the mortgage finance or financial system;

(7) The degree to which the new product furthers fair housing and fair lending; and

(8) Such other factors as determined appropriate by the Director.

§ 1253.5 Notice of new activity.

(a) Before commencing a new activity, an Enterprise must submit a notice of new activity to FHFA. An Enterprise may request prior consultation with FHFA about whether a notice of new activity is required.

(b) In support of its notice of new activity, the Enterprise shall submit thorough, complete, and specific information as described under § 1253.9(a). FHFA will evaluate the notice of new activity to determine if the submission contains sufficient information to enable the Director to determine whether the new activity is a new product subject to prior approval. Once FHFA makes the determination that the submission is complete, FHFA will notify the Enterprise that the submission is ''received'' for purposes of 12 U.S.C. 4541(e)(2)(B).

(c) Nothing in this regulation limits or restricts FHFA from reviewing a notice of new activity under any other applicable law, under the Director's authority to review for safety and soundness, or to determine whether the activity complies with the Enterprise's authorizing statute. FHFA may conduct such a review as part of its determination that the notice of new activity submission is complete.

(d) No later than 15 days after FHFA notifies the Enterprise that the submission is received, the Director will make a determination on the notice of new activity and will notify the Enterprise accordingly. If the Director determines that the new activity is a new product, the Enterprise must elect to either submit a request for prior approval of the new product under § 1253.6 or discontinue its plan to offer the new product to the market.

(e) If the Director determines that the new activity is not a new product, or if after the passage of 15 days the Director does not make a determination whether the new activity is a new product, the Enterprise may commence the new activity. The Director may establish terms, conditions, or limitations on the Enterprise's engagement in the new activity as the Director determines to be appropriate and with which the Enterprise must comply in order to engage in the new activity.

(f) If the Director does not make a determination within the 15-day period, the absence of such determination does not limit or restrict the Director's safety and soundness authority or the Director's authority to review the new activity to confirm that the activity is consistent with the Enterprise's authorizing statute.

§ 1253.6 Request for prior approval of a new product; public notice; standards for approval.

(a) An Enterprise must submit a request for prior approval of a new product to FHFA before offering a new product to the market.

(1) An Enterprise may submit a request for prior approval of a new product if the Director determines that a new activity is a new product under § 1253.5(d) or, following consultation with FHFA, if the Director authorizes the Enterprise to submit such a request without first submitting a notice of new activity. An Enterprise must submit a request for prior approval of a new product to FHFA before offering a new product to the market.

(2) In support of its request for prior approval of a new product, the Enterprise shall submit thorough, complete, and specific information as described under § 1253.9(b).

(3) FHFA will evaluate the request to determine if the submission contains sufficient information for FHFA to prepare a public notice such that the public will be able to provide fully informed comments on the new product. Once FHFA makes the determination that the submission is complete, FHFA will notify the Enterprise that the submission is ''received'' for purposes of 12 U.S.C. 4541(c)(2).

(b) Following FHFA's determination that a submission is complete, FHFA will publish a public notice soliciting comments on the new product on FHFA's website and in the **Federal Register** without delay.

(1) The public notice will describe the new product and will include such information from the request for prior approval of a new product as necessary to provide the public with sufficient notice and opportunity to comment on the new product. The public notice will provide instructions for the submission of public comments.

(2) The public will have 30 days from the date that the public notice is published in the **Federal Register** to provide comments on the new product.

(3) The Director will consider all public comments received by the closing date of the comment period.

(c) No later than 30 days after the end of the public comment period, the Director will provide the Enterprise with a written determination on whether it may proceed with the new product. The written determination will specify the grounds for the Director's determination.

(d) The Director may approve the new product if the Director determines that the new product:

(1) In the case of Fannie Mae, is authorized under 12 U.S.C. 1717(b)(2), (3), (4), or (5) or 12 U.S.C. 1719; or

(2) In the case of Freddie Mac, is authorized under 12 U.S.C. 1454(a)(1), (4), or (5); and

(3) Is in the public interest; and

(4) Is consistent with the safety and soundness of the Enterprise or the mortgage finance system.

(e) The Director may consider the factors provided in § 1253.4(b) when determining whether a new product is in the public interest.

(f) The Director may establish terms, conditions, or limitations on the Enterprise's offering of the new product with which the Enterprise must comply in order to offer the new product.

(g) If the Director disapproves the new product, the Enterprise may not offer the new product.

(h) If the Director does not make a determination within 30 days after the end of the public comment period, the Enterprise may offer the new product. The absence of such a determination within 30 days does not limit or restrict the Director's safety and soundness authority or the Director's authority to review the new product to confirm that the product is consistent with the Enterprise's authorizing statute.

(i) The Director may request any information in addition to that supplied in the completed request for prior approval of a new product if, as a result of public comment or otherwise in the course of considering the request, the Director believes that the information is

necessary for the Director's decision. The Director may disapprove a new product if the Director does not receive the information requested from the Enterprise in sufficient time to permit adequate evaluation of the information within the time periods set forth in this section.

§ 1253.7 Temporary approval of a new product.

(a) The Director may approve a new product without first seeking public comment as described in § 1253.6 if:

(1) In addition to the information required by § 1253.9(b), the Enterprise submits a specific request for temporary approval that describes the exigent circumstances that make the delay associated with a 30-day public comment period contrary to the public interest and the Director determines that exigent circumstances exist and that delay associated with first seeking public comment would be contrary to the public interest; or

(2) Notwithstanding the absence of a request by the Enterprise for temporary approval, the Director determines on the Director's own initiative that there are exigent circumstances that make the delay associated with first seeking public comment contrary to the public interest.

(b) The Director may impose terms, conditions, or limitations on the temporary approval to ensure that the new product offering is consistent with the factors in § 1253.6(d).

(c) If the Director grants temporary approval, the Director will notify the Enterprise in writing of the Director's decision and include the period for which it is effective and any terms, conditions or limitations. Upon granting of temporary approval, FHFA will also publish the request for public comment to begin the process for permanent approval in accordance with § 1253.6.

(d) If the Director denies a request for temporary approval, the Director will notify the Enterprise in writing of the Director's decision and will evaluate the new product in accordance with this section.

§ 1253.8 Substantially similar activities.

(a) An Enterprise shall notify FHFA of its intent to commence an activity that is substantially similar to any of the following activities at least 15 days prior to offering the activity:

(1) The automated loan underwriting system of an Enterprise that was in existence as of July 30, 2008, including any enhancement, alteration, or modification to the technology, operating system, or software to operate the automated loan underwriting system;

(2) Any enhancement, alteration, or modification to mortgage terms and conditions or underwriting criteria relating to mortgages that are purchased or guaranteed by an Enterprise, provided that such activity does not alter the underlying transaction so as to include services or financing, other than residential mortgage financing; or

(3) A new product that the Director has approved for either Enterprise under § 1253.6(a) through (f) or § 1253.7 or a new product that is otherwise available to either Enterprise under § 1253.6(h).

(b) The Director may determine that an activity is substantially similar to an activity described in paragraph (a)(1) or (2) of this section, if the activity is:

(1) A technology system that applies mortgage terms and conditions or underwriting criteria to residential mortgages that are purchased or guaranteed by an Enterprise; or

(2) An enhancement, alteration, or modification to the technology, operating system, or software to operate a technology system described in paragraph (b)(1) of this section.

(c) The Director may determine that an activity is substantially similar to an activity described in paragraph (a)(3) of this section, if the activity:

(1) Requires the same or a similar resource, type of data, policy, process, and infrastructure;

(2) Entails the same or similar levels of credit risk, market risk, and operational risk to the Enterprise; and

(3) Involves the same or a similar category of borrower, investor, counterparty, and collateral.

(d) The notification is not required to be a notice of new activity. The notification shall include the name and a complete and specific description of the activity, as well as an explanation of why the Enterprise believes the activity qualifies as a substantially similar activity under paragraph (a) of this section.

(e) Public notice and comment is not required in connection with offering substantially similar activities.

(f) If the Director determines an activity is not a substantially similar activity, the Enterprise must submit a notice of new activity under § 1253.5 or a request for prior approval of a new product under § 1253.6 and may not proceed or continue with the activity except pursuant to the requirements in this part.

§ 1253.9 New activity and new product submission requirements.

(a) A notice of new activity must provide the following items of information and appropriate supporting documentation. The corresponding paragraph number should be listed with the relevant information provided:

(1) Provide the name of the new activity and a complete and specific description of the new activity that identifies under which paragraph(s) of § 1253.3(a) the activity is described.

(2) Describe the business rationale, the intended market, the business line, and what products are currently being offered or are proposed to be offered under such business line. Also, include a description of any market research performed relating to the new activity.

(3) State the anticipated commencement date for the new activity. Provide analysis, including assumptions, development expenses, any applicable fees, expectations for the impact of and projections for the quarterly size (for example, in terms of cost, personnel, volume of activity, or risk metrics) of the new activity for at least the first 12 months of deployment, as well as the impact of the new activity on the risk profile of the Enterprise and the key controls for the following risks: credit, market, and operational.

(4) If the new activity is a pilot, include the parameters, such as duration, volume of activity, and performance. If the new activity is the result of a pilot, include an analysis on the effectiveness of the pilot that describes the pilot objectives and success criteria; volume of activity; performance; risk metrics and controls; and the modifications made for a broader offering and rationale.

(5) Provide a fair housing and fair lending self-evaluation of the new activity. The self-evaluation should, at a minimum, include data on the predicted impact of the new activity for protected class categories; a summary of reasonable alternatives considered; if disparities are identified, the business justification for the new activity; and the extent to which the activity furthers fair housing and fair lending.

(b) A request for prior approval of a new product must provide the following items of information with appropriate supporting documentation. The corresponding paragraph number should be listed with the relevant information provided:

(1) Provide the information required for a notice of new activity as identified in paragraph (a) of this section.

(2) Describe the business requirements for the new product including technology requirements. Describe the Enterprise business units involved in conducting the new product, including any affiliation or subsidiary relationships, any third-party

relationships, and the roles of each. Describe the reporting lines and planned oversight of the new product.

(3) Provide a legal analysis as to whether the new product is—

(i) In the case of Fannie Mae, authorized under 12 U.S.C. 1717(b)(2), (3), (4), or (5) or 12 U.S.C. 1719; or

(ii) In the case of Freddie Mac, authorized under 12 U.S.C. 1454(a)(1), (4), or (5).

(4) Provide copies of all notice and application documents, including any application for patents or trademarks, the Enterprise has submitted to other Federal, State or local government regulators relating to the new product.

(5) Describe the impact of the new product on the public interest and provide information to address the factors listed in § 1253.4(b).

(6) Describe how the new product is consistent with the safety and soundness of the Enterprise or the mortgage finance system.

(7) Explain any accounting treatment proposed for the new product.

(c) FHFA may require an Enterprise to submit such further information as the Director deems necessary to make a determination on a notice of new activity or a request for prior approval of a new product, at the time of the original submission or any time thereafter.

(d) An Enterprise shall certify, through an executive officer, that a notice of new activity or a request for prior approval of a new product and any supporting material submitted to FHFA pursuant to this part contain no material misrepresentations or omissions. FHFA may review and verify any information filed in connection with a notice of new activity or request for prior approval of a new product.

§ 1253.10 Public disclosure.

In addition to information disclosed in the public notice on a new product, FHFA will make public information related to the Director's determinations on new activity and new product submissions within a reasonable time period after the end of the calendar year during which either Enterprise filed such a submission. Any disclosure under this paragraph will omit any confidential and proprietary information not previously disclosed as part of a public notice on a new product.

§ 1253.11 Preservation of authority.

The Director's exercise of the Director's authority pursuant to the prior approval authority for products under 12 U.S.C. 4541, and this regulation, in no way restricts:

(a) The safety and soundness authority of the Director over all new and existing products or activities; or

(b) The authority of the Director to review all new and existing products or activities to determine that such products or activities are consistent with the authorizing statute of an Enterprise.

Sandra L. Thompson,

Director, Federal Housing Finance Agency.

[FR Doc. 2022–27942 Filed 12–23–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0465; Project Identifier AD–2022–00330–R; Amendment 39–22288; AD 2022–27–03]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–20–10 for certain Leonardo S.p.a. Model AB139 and AW139 helicopters. AD 2021–20–10 required removing from service a certain part-numbered main gearbox (MGB) spherical bearing lock nut (lock nut) that is installed on certain part-numbered MGBs and replacing it with a newly designed MGB lock nut. AD 2021–20–10 also prohibited installing any MGB with the affected MGB lock nut and prohibited installing any affected MGB lock nut on any helicopter. Since the FAA issued AD 2021–20–10, it was discovered that a part number (P/N) was incorrectly listed and that the applicability needed to be clarified. This AD retains the requirements of AD 2021–20–10 and clarifies the applicability. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 31, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 22, 2021 (86 FR 57574, October 18, 2021).

ADDRESSES: For service information identified in this final rule, contact Leonardo S.p.a. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G. Agusta 520, 21017 C. Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *customerportal.leonardocompany.com/en-US/*. 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. Service information that is incorporated by reference is also available at *regulations.gov* by searching for and locating Docket No. FAA–2022–0465.

Examining the AD Docket

You may examine the AD docket at *regulations.gov*by searching for and locating Docket No. FAA–2022–0465; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

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

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–20–10, Amendment 39–21748 (86 FR 57574, October 18, 2021) (AD 2021–20–10). AD 2021–20–10 applied to Leonardo S.p.a. Model AB139 and AW139 helicopters, without MGB lock nut P/N 3G6320A09152 installed and with MGB P/N 3G6320A00131, 3G6320A00132, 3G6320A00133, 3G6320A00134, 3G6320A00135, 3G6320A00136, 3G6320A22031, 4G6320A00132, or 4G6320A00133 installed; or MGB P/N 3G320A00133 with serial number (S/N) M23 installed, or MGB P/N 3G6320A00134, with S/N M6, N76, N92, P124, P129, P131, P162, P184, Q230, Q243, Q249, R272, V21, V39, V96, V163, V211, V241, V272, V281, V384, V386, or V622 installed; or MGB P/N 3G6320A00136 with S/N AW1, AW2, AW3, AW5, or AW10 installed.

AD 2021–20–10 required, within 100 hours time-in-service (TIS), or during the next scheduled MGB overhaul, whichever occurs first after the effective

date of the AD, removing a certain part-numbered MGB lock nut from service and replacing it with a different part-numbered MGB lock nut. AD 2021–20–10 also prohibited installing an MGB having an affected MGB lock nut on any helicopter and also prohibited installing an affected MGB lock nut on any helicopter as of the effective date of the AD.

AD 2021–20–10 was prompted by a series of EASA ADs beginning with EASA AD 2019–0036, dated February 15, 2019 (EASA AD 2019–0036), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for all serial-numbered Leonardo S.p.a. Helicopters (formerly Finmeccanica S.p.A, AgustaWestland S.p.A., Agusta S.p.A.; and AgustaWestland Philadelphia Corporation, formerly Agusta Aerospace Corporation) Model AB139 and AW139 helicopters. EASA advised that an occurrence was reported of a cracked MGB lock nut P/N 3G6310A09151, which is used to keep the planetary gears in position. EASA AD 2019–0036 required replacing each MGB lock nut with an airworthy MGB lock nut. EASA advised this condition, if not detected and corrected, could lead to failure of the MGB planetary gears, resulting in loss of control of the helicopter.

After EASA issued EASA AD 2019–0036, an additional occurrence was reported of a cracked MGB lock nut P/N 3G6320A09151. Accordingly, EASA superseded EASA AD 2019–0036 with EASA AD 2019–0174, dated July 18, 2019 (EASA AD 2019–0174), which retained the requirements of EASA AD 2019–0036 but reduced the compliance times. After EASA issued EASA AD 2019–0174, Leonardo Helicopters issued Alert Service Bulletin No. 139–609, dated December 18, 2019, to provide instructions for replacing the affected MGB lock nut with MGB lock nut P/N 3G6320A09152, which has a redesigned flange reducing the stress at the bearing nut locations where cracks were detected.

Accordingly, EASA then issued EASA AD 2020–0011, dated January 29, 2020, and corrected January 30, 2020 (EASA AD 2020–0011), which superseded EASA AD 2019–0174, and partially retained the requirements of EASA AD 2019–0174. EASA AD 2020–0011 revised the compliance times in EASA AD 2019–0174, required replacing each affected MGB lock nut with a newly designed MGB lock nut, and prohibited installing an affected MGB on any helicopter. After EASA issued EASA AD 2020–0011, EASA identified certain MGB part numbers that were inadvertently categorized incorrectly and therefore listed in the wrong group of helicopters. Accordingly, EASA issued EASA AD 2020–0011R1, dated November 20, 2020 (EASA AD 2020–011R1), thereby revising EASA AD 2020–0011. EASA AD 2020–0011R1 retained the requirements of EASA AD 2020–0011 and corrected Appendix 1 of EASA AD 2020–0011.

After EASA issued EASA AD 2020–0011R1, Leonardo Helicopters issued Alert Service Bulletin No. 139–609, Revision A, dated April 13, 2021, which identifies an additional part-numbered MGB, which is also affected by the unsafe condition. Accordingly, EASA superseded EASA AD 2020–0011R1 with EASA AD 2021–0121, dated May 4, 2021 (EASA AD 2021–0121). EASA AD 2021–0121 adds an additional part-numbered MGB with a certain S/N to the list of affected parts. EASA AD 2021–0121 retains the requirements of EASA AD 2020–0011R1, and corrects Table 1 and Appendix 1 of EASA AD 2020–0011R1.

Accordingly, EASA AD 2021–0121 requires replacing each affected MGB lock nut with a newly designed MGB lock nut, and prohibits installing an affected MGB on any helicopter.

The NPRM published in the **Federal Register** on April 20, 2022 (87 FR 23477). The NPRM was prompted by the discovery that MGB P/N 3G6320A00133 was incorrectly listed as MGB P/N 3G320A00133 in both the preamble and applicability paragraph of AD 2021–20–10. Also, the FAA determined that all MGBs, regardless of S/N, are affected by the unsafe condition. Therefore, the NPRM proposed to remove any reference to S/Ns in the applicability. In addition, the NPRM included the total U.S. fleet costs, which were inadvertently excluded in AD 2021–20–10. In the NPRM, the FAA also proposed to retain all of the requirements of AD 2021–20–10.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from three commenters. The commenters were Leonardo Helicopters, Bristow Group, and Chevron Aviation. All commenters requested a change to the compliance time and two made a statement concerning who can perform the service task. The following presents the comments received on the NPRM and the FAA's response to each comment.

Requests To Change the Compliance Time To Upgrade the MGB Lock Nuts

All commenters referred to an FAA-approved global Alternative Method of Compliance (AMOC) to AD 2021–20–10 and two commenters requested that the FAA change the proposed AD's compliance time to align with the global AMOC. The other commenter specifically requested that the compliance time approved in the global AMOC of 28,000 landings or during the next scheduled MGB overhaul be incorporated into the compliance time of the proposed AD.

The FAA agrees; however, instead of revising the Required Actions paragraph, the FAA has revised the AMOC paragraph by allowing the AMOC previously approved for AD 2021–20–10 as an approved AMOC for the corresponding requirements in paragraph (g) of this AD.

Required Actions

Two commenters noted that replacing the lock nut can only be performed by Leonardo at the overhaul level, but requested no change to the required actions of the proposed AD; the FAA, therefore, made no changes in this regard.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, including correcting a part number in paragraph (g)(2) of the required actions, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Leonardo Helicopters Alert Service Bulletin No. 139–609, Revision A, dated April 13, 2021, which the Director of the Federal Register approved for incorporation by reference as of November 22, 2021 (86 FR 57574, October 18, 2021).

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 also reviewed Leonardo Helicopters Alert Service Bulletin No. 139–567, Revision B, dated October 18, 2019, which provides additional

information for replacing the MGB lock nut.

Differences Between This AD and EASA AD 2021–0121

EASA AD 2021–0121 requires a compliance time based on number of landings, whereas this AD requires a compliance time based on hours TIS. The service information referenced in EASA AD 2021–0121 requires submitting certain information and parts to Leonardo, whereas this AD does not. EASA AD 2021–0121 applies to all serial-numbered Model AB139 and AW139 helicopters, whereas this AD applies to all Model AB139 and AW139 helicopters, regardless of S/N, with a certain part-numbered MGB lock nut and MGB installed.

Costs of Compliance

The FAA estimates that this AD affects 130 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Replacing each affected MGB lock nut with a newly designed MGB lock nut takes about 190 work-hours (during next MGB overhaul) and parts cost about $7,600 for an estimated cost of $23,750 per helicopter and $3,087,500 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2021–20–10, Amendment 39–21748 (86 FR 57574, October 18, 2021); and

■ b. Adding the following new airworthiness directive:

2022–27–03 Leonardo S.p.a.: Amendment 39–22288; Docket No. FAA–2022–0465; Project Identifier AD–2022–00330–R.

(a) Effective Date

This airworthiness directive (AD) is effective January 31, 2023.

(b) Affected ADs

This AD replaces AD 2021–20–10, Amendment 39–21748 (86 FR 57574, October 18, 2021) (AD 2021–20–10).

(c) Applicability

This AD applies to Leonardo S.p.a. Model AB139 and AW139 helicopters, certificated in any category, with a main rotor gearbox (MGB) part number (P/N) 3G6320A00131, 3G6320A00132, 3G6320A00133, 3G6320A00134, 3G6320A00135, 3G6320A00136, 3G6320A22031, 4G6320A00132, or 4G6320A00133, and MGB spherical bearing lock nut (lock nut) P/N 3G6320A09151 installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6320, Main Rotor Gearbox.

(e) Unsafe Condition

This AD was prompted by a cracked MGB lock nut. The FAA is issuing this AD to replace an affected MGB lock nut with a new MGB lock nut. The unsafe condition, if not addressed, could result in failure of the MGB planetary gears, resulting in loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 100 hours time-in-service, or during the next scheduled MGB overhaul, whichever occurs first after November 22, 2021 (the effective date of AD 2021–20–10), remove each MGB lock nut P/N 3G6320A09151 from service and replace with MGB lock nut P/N 3G6320A09152 in accordance with Annex A, steps 1 through 17, of Leonardo Helicopters Alert Service Bulletin No. 139–609, Revision A, dated April 13, 2021, except you are not required to send parts to Leonardo Helicopters.

Note 1 to paragraph (g)(1): Leonardo Helicopters service information refers to an MGB lock nut as a ring nut.

(2) As of November 22, 2021 (the effective date of AD 2021–20–10), do not install any MGB having MGB lock nut P/N 3G6320A09151 on any helicopter, and do not install any MGB lock nut P/N 3G6320A09151 on any helicopter.

(h) Special Flight Permits

Special flight permits are prohibited.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(3) AMOCs approved previously for AD 2021–20–10 are approved as AMOCs for the corresponding requirements in paragraph (g) of this AD.

(j) Related Information

(1) Refer to EASA AD 2021–0121, dated May 4, 2021, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–0465.

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

(k) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on November 22, 2021 (86 FR 57574, October 18, 2021).

(i) Leonardo Helicopters Alert Service Bulletin No. 139–609, Revision A, dated April 13, 2021.

(ii) [Reserved]

(4) For service information identified in this AD, contact Leonardo S.p.a. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G. Agusta 520, 21017 C. Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *customerportal.leonardocompany.com/en-US/.*

(5) You may view this service information at 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.

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

Issued on December 20, 2022.

Christina Underwood,

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

[FR Doc. 2022–28090 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1306; Project Identifier AD–2022–01040–E; Amendment 39–22289; AD 2022–27–04]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Pratt & Whitney (PW) PW1519G, PW1521G, PW1521G–3, PW1521GA, PW1524G, PW1524G–3, PW1525G, and PW1525G–3 model turbofan engines. This AD was prompted by an uncommanded dual engine shutdown upon landing, resulting in compromised braking capability due to the loss of engine power and hydraulic systems. This AD requires removal from service of certain electronic engine control (EEC) full authority digital engine control (FADEC) software versions and replacement with updated software. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 31, 2023.

ADDRESSES: *AD Docket:* You may examine the AD docket at *regulations.gov* by searching for and locating Docket No. FAA–2022–1306; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mark Taylor, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7229; email: *Mark.Taylor@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all PW PW1519G, PW1521G, PW1521G–3, PW1521GA, PW1524G, PW1524G–3, PW1525G, and PW1525G–3 model turbofan engines. The NPRM published in the **Federal Register** on October 25, 2022 (87 FR 64397). The NPRM was prompted by a report that an airplane experienced an uncommanded dual engine shutdown upon landing, resulting in compromised braking capability due to the loss of engine power and hydraulic systems. A subsequent investigation determined that the sequence of the auto-throttle increasing throttle to maintain Mach number, immediately followed by pilot command to decrease throttle to idle, caused a transient disagreement between actual and commanded thrust. This disagreement triggered the thrust control malfunction (TCM) detection logic and resulted in dual engine shutdown once the weight on wheels signal was activated upon landing. The installed EEC FADEC software version latches the fault and allows the engine to continue operation as commanded but shuts down the engine upon landing. The manufacturer identified the situations that could trigger the TCM logic erroneously and updated the EEC FADEC software. This software update makes corrective improvements to the TCM logic, including revised criteria for triggering the TCM logic and establishing criteria that permit the TCM logic to unlatch during flight. In the NPRM, the FAA proposed to require removal from service of certain EEC FADEC software versions and replacement with a software version eligible for installation. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received one comment, from Air Line Pilots Association, International (ALPA). ALPA supported the NPRM without change.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information

The FAA reviewed PW Service Bulletin (SB) PW1000G–A–73–00–0054–00A–930A–D, Issue No. 002, dated June 20, 2022. This service information specifies procedures for replacing or modifying the EEC to incorporate FADEC software version V2.11.14.

Costs of Compliance

The FAA estimates that this AD affects 147 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Upgrade EEC FADEC Software	2 work-hours × $85 per hour = $170	$0	$170	$24,990

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–27–04 Pratt & Whitney: Amendment 39–22289; Docket No. FAA–2022–1306; Project Identifier AD–2022–01040–E.

(a) Effective Date

This airworthiness directive (AD) is effective January 31, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pratt & Whitney PW1519G, PW1521G, PW1521G–3, PW1521GA, PW1524G, PW1524G–3, PW1525G, and PW1525G–3 model turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7600, Engine Controls.

(e) Unsafe Condition

This AD was prompted by an uncommanded dual engine shutdown upon landing, resulting in compromised braking capability due to the loss of engine power and hydraulic systems. The FAA is issuing this AD to prevent compromised braking capability due to uncommanded dual engine shutdown upon landing. The unsafe condition, if not addressed, could result in runway excursion.

(f) Compliance

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

(g) Required Actions

For affected engines with installed electronic engine control (EEC) full authority digital engine control (FADEC) software version earlier than V2.11.14.1, within 12 months after the effective date of this AD, remove the EEC FADEC software and replace with an EEC FADEC software version eligible for installation.

(h) Definitions

For the purpose of this AD, ''EEC FADEC software version eligible for installation'' is EEC FADEC software version V2.11.14.1 or later.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO 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) of this AD and email to: *ANE-AD-AMOC@faa.gov.*

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

(j) Related Information

For more information about this AD, contact Mark Taylor, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7229; email: *Mark.Taylor@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued on December 20, 2022.

Christina Underwood,

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

[FR Doc. 2022–28091 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1574; Project Identifier MCAI–2022–01362–T; Amendment 39–22274; AD 2022–25–18]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Airplanes; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comment; correction.

SUMMARY: The FAA is correcting an airworthiness directive (AD) that was published in the **Federal Register**. That AD applies to certain BAE Systems (Operations) Limited Model BAe 146 and Model Avro 146–RJ series airplanes. As published, the identity of certain airplanes in the preamble and regulatory

text, and one paragraph reference in the regulatory text, are incorrect. This document corrects those errors. In all other respects, the original document remains the same.

DATES: This correction is effective December 27, 2022. The effective date of AD 2022–25–18 remains December 27, 2022. The date for submitting comments on AD 2022–25–18 remains January 26, 2023.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 27, 2022 (87 FR 75915, December 12, 2022).

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of May 2, 2005 (70 FR 15574, March 28, 2005; corrected April 14, 2005 (70 FR 19681)).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1574; 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 correction, the final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For U.K. CAA material incorporated by reference in this AD, contact Civil Aviation Authority, Aviation House, Beehive Ring Road, Crawley, West Sussex RH6 0YR, United Kingdom; telephone +44(0) 330 022 4401; email *continued.airworthiness@caa.co.uk;* website *caa.co.uk.*
- For BAE Systems (Operations) Limited service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* website *baesystems.com/Businesses/RegionalAircraft/index.htm.*
- For Messier-Dowty service information identified in this AD, contact Messier-Dowty: Messier Services Americas, Customer Support Center, 45360 Severn Way, Sterling, VA 20166–8910; telephone 703–450–8233; fax 703–404–1621; website *techpubs.services/messier-dowty.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2022–1574.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3228; email *todd.thompson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about AD 2022–25–18. Submit comments as instructed in AD 2022–25–18, Amendment 39–22274 (87 FR 75915, December 12, 2022) (AD 2022–25–18).

Background

AD 2022–25–18 requires repetitive inspections for cracking of the main landing gear (MLG) side stay outer links, and corrective actions if necessary. AD 2022–25–18 also provides an optional terminating action for the repetitive inspections, and prohibits the installation of affected parts under certain conditions. That AD applies to certain BAE Systems (Operations) Limited Model BAe 146 and Model Avro 146–RJ series airplanes.

Need for the Correction

As published, the identity of certain airplanes specified in the preamble and regulatory text, and one paragraph reference specified in the regulatory text, are incorrect in AD 2022–25–18.

In three locations in AD 2022–25–18, affected airplanes are incorrectly identified as ''Model Avro 146–RJ–RJ70A'' airplanes. Those airplanes are correctly identified as ''Model Avro 146–RJ70A airplanes.'' The errors are located in the ''Differences Between This AD and the MCAI'' section of the preamble and paragraph (c) of AD 2022–25–18.

In addition, paragraph (l)(1) of AD 2022–25–18 incorrectly refers to paragraph (n) of the AD for the contact information to send requests for approval of alternative methods of compliance. That contact information is correctly found in paragraph (m) of this AD.

Related Service Information Under 1 CFR Part 51

U.K. CAA AD G–2022–0018, dated October 18, 2022, specifies procedures for doing repetitive detailed inspections for cracking of the MLG side stay outer link and replacement if necessary.

The FAA reviewed BAE Systems (Operations) Limited Alert Service Bulletin ASB.32–A189, dated September 16, 2022. This service information identifies the affected parts as MLG side stay outer links having Safran Landing Systems part numbers 200884304, 200884305, 200884346, 200884347, 201105300, 201105301, 201105308, 201105309, 201299300, 201299301, 201299305, or 201299306, and describes procedures for doing, among other actions, repetitive detailed inspections for cracking of MLG side stay outer links and replacement if necessary.

The FAA also reviewed Messier-Dowty Service Bulletin 146–32–147, dated May 29, 2001, which identifies the affected MLG side stay outer links for AD 2005–06–14, Amendment 39–14024 (70 FR 15574, March 28, 2005; corrected April 14, 2005 (70 FR 19681)).

This AD also requires BAE Systems (Operations) Limited Inspection Service Bulletin ISB.32–156, Revision 1, dated July 3, 2001, which the Director of the Federal Register approved for incorporation by reference as of May 2, 2005 (70 FR 15574, March 28, 2005; corrected April 14, 2005 (70 FR 19681)).

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

Correction of Publication

This document corrects multiple errors and correctly adds the AD as an amendment to 14 CFR 39.13. Although no other part of the preamble or regulatory information has been corrected, the FAA is publishing the entire rule in the **Federal Register**.

The effective date of this AD remains December 27, 2022.

Since this action only corrects a model designation and a paragraph reference, it has no adverse economic impact and imposes no additional burden on any person. Therefore, the FAA has determined that notice and public procedures are unnecessary.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the

Federal Aviation Regulations (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 [Corrected]

■ 2. The FAA amends § 39.13 by:
■ a. Removing Airworthiness Directive (AD) 2005–06–14, Amendment 39–14024 (70 FR 15574, March 28, 2005; corrected April 14, 2005 (70 FR 19681)); and
■ b. Adding the following new AD:

2022–25–18 BAE Systems (Operations) Limited: Amendment 39–22274; Docket No. FAA–2022–1574; Project Identifier MCAI–2022–01362–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 27, 2022.

(b) Affected ADs

This AD replaces AD 2005–06–14, Amendment 39–14024 (70 FR 15574, March 28, 2005; corrected April 14, 2005 (70 FR 19681)) (AD 2005–06–14).

(c) Applicability

This AD applies to BAE Systems (Operations) Limited Model BAe 146–100A, –200A, and –300A airplanes and Model Avro 146–RJ70A, 146–RJ85A, and 146–RJ100A airplanes, certificated in any category, with main landing gear (MLG) side stay outer links having Safran Landing Systems part number 200884304, 200884305, 200884346, 200884347, 201105300, 201105301, 201105308, 201105309, 201299300, 201299301, 201299305, or 201299306.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Unsafe Condition

This AD was prompted by reports of cracking on the shoulders of a main landing gear (MLG) side stay outer link. The FAA is issuing this AD to address cracking of the MLG side stay outer link. The unsafe condition, if not addressed, could lead to failure of the side stay outer link and MLG collapse, which could result in a runway departure, and could result in the engine or wing contacting the ground. The engine or wing contacting the ground could result in damage to the airplane, an increased risk of fire, the airplane flipping, and injury to occupants.

(f) Compliance

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

(g) Retained Inspections, With New Terminating Action

This paragraph restates the requirements of paragraph (f) of AD 2005–06–14, with new terminating action. For airplanes having any side stay identified in Messier-Dowty Service Bulletin 146–32–147, dated May 29, 2001: At the applicable time specified in paragraph (g)(1) or (2) of this AD, perform a detailed inspection for cracks of the outer links on the MLG side stays, in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.32–156, Revision 1, dated July 3, 2001. Repair cracks before further flight in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.32–156, Revision 1, dated July 3, 2001. Thereafter, repeat the inspection at intervals not to exceed 2,000 flight cycles, until the actions specified in paragraph (h) of this AD have been done or the initial inspection required by paragraph (i) of this AD has been done. Although BAE Systems (Operations) Limited Inspection Service Bulletin ISB.32–156, Revision 1, dated July 3, 2001, specifies to report certain information to the manufacturer, this AD does not require a report.

(1) If the number of flight cycles accumulated on the side stay can be positively determined: Inspect before the accumulation of 2,000 total flight cycles on the side stay, or within 500 flight cycles after May 2, 2005 (the effective date of AD 2005–06–14), whichever occurs later.

(2) If the number of flight cycles accumulated on the side stay cannot be positively determined: Inspect within 500 flight cycles after May 2, 2005 (the effective date of AD 2005–06–14).

(h) Retained Optional Terminating Action for Paragraph (g) of This AD, With No Changes

This paragraph restates the optional terminating action of paragraph (g) of AD 2005–06–14, with no changes. Relocation of each affected grease nipple to the upper surface of the outer link of the MLG side stays terminates the repetitive inspections required by paragraph (g) of this AD, if the relocation action is done in accordance with paragraph 2.C. of the Accomplishment Instructions of BAE Systems (Operations) Limited Inspection Service Bulletin ISB.32–156, Revision 1, dated July 3, 2001.

(i) New Requirements

Except as specified in paragraph (j) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, United Kingdom Civil Aviation Authority AD G–2022–0018, dated October 18, 2022 (U.K. CAA AD G–2022–0018).

(j) Exceptions to U.K. CAA AD G–2022–0018

(1) Where U.K. CAA AD G–2022–0018 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of U.K. CAA AD G–2022–0018 does not apply to this AD.

(3) Where paragraph (2) of U.K. CAA AD G–2022–0018 refers to ''discrepancies (*i.e.* cracks or other adverse findings),'' replace the text ''discrepancies (*i.e.* cracks or other adverse findings),'' with ''any cracking.''

(4) Where U.K. CAA AD G–2022–0018 refers to ASB.32–A189, this AD requires using BAE Systems (Operations) Limited Alert Service Bulletin ASB.32–A189, dated September 16, 2022.

(k) No Reporting Requirement

Although BAE Systems (Operations) Limited Alert Service Bulletin ASB.32–A189, dated September 16, 2022, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(l) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (m) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards 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, International Validation Branch, FAA; or the United Kingdom Civil Aviation Authority (U.K. CAA); or BAE Systems (Operations) Limited's U.K. CAA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Additional Information

For more information about this AD, contact Todd Thompson, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 206–231–3228; email *todd.thompson@faa.gov.*

(n) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on December 27, 2022.

(i) BAE Systems (Operations) Limited Alert Service Bulletin ASB.32–A189, dated September 16, 2022.

(ii) Messier-Dowty Service Bulletin 146–32–147, dated May 29, 2001.

(iii) United Kingdom Civil Aviation Authority (U.K. CAA) AD G–2022–0018, dated October 18, 2022.

(4) The following service information was approved for IBR on May 2, 2005 (70 FR 15574, March 28, 2005; corrected April 14, 2005 (70 FR 19681)).

(i) BAE Systems (Operations) Limited Inspection Service Bulletin ISB.32–156, Revision 1, dated July 3, 2001.

(ii) [Reserved]

(5) For BAE Systems (Operations) Limited service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com;* website *baesystems.com/Businesses/RegionalAircraft/index.htm.*

(6) For Messier-Dowty service information identified in this AD, contact Messier-Dowty: Messier Services Americas, Customer Support Center, 45360 Severn Way, Sterling, VA 20166–8910; telephone 703–450–8233; fax 703–404–1621; website *techpubs.services/messier-dowty.com.*

(7) For U.K. CAA AD G–2022–0018, contact Civil Aviation Authority, Aviation House, Beehive Ring Road, Crawley, West Sussex RH6 0YR, United Kingdom; telephone +44(0) 330 022 4401; email *continued.airworthiness@caa.co.uk;* website *caa.co.uk.*

(8) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1574.

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

Issued on December 21, 2022.

Christina Underwood,

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

[FR Doc. 2022–28211 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. FAA–2007–27602; Amdt. No. 91–339C]

RIN 2120–AL78

Prohibition Against Certain Flights in the Territory and Airspace of Somalia

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This action amends and extends the prohibition against certain flight operations in the territory and airspace of Somalia at altitudes below Flight Level 260 (FL260) by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier. The FAA is amending the flight prohibition to permit overwater operations in the territory and airspace of Somalia at altitudes below FL260 to the extent necessary for climb-outs from, and descents into, Djibouti Ambouli International Airport (HDAM) in the Addis Ababa Flight Information Region (FIR) (HAAA), subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Djibouti and consistent with air traffic control instructions. Operators climbing out of or descending into Djibouti Ambouli International Airport (HDAM) must remain overwater while operating in the territorial airspace of Somalia at altitudes below FL260 and must operate either on a published instrument procedure or under the direction of air traffic control. The FAA determined the risk to the safety of such operations is low. However, due to increasing safety-of-flight risks to U.S. civil aviation in the rest of the territory and airspace of Somalia at altitudes below FL260 from extremist and militant activity, the FAA also extends the expiration date of this rule from January 7, 2023, until January 7, 2027. The FAA also republishes the approval process and exemption information for this Special Federal Aviation Regulation (SFAR), consistent with other recently published flight prohibition SFARs.

DATES: This final rule is effective on December 27, 2022.

FOR FURTHER INFORMATION CONTACT: Bill Petrak, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–8166; email *bill.petrak@faa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This action amends and extends SFAR No. 107, title 14 Code of Federal Regulations (CFR) 91.1613, which prohibits certain flight operations in the territory and airspace of Somalia at altitudes below FL260 by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except when the operator of such aircraft is a foreign air carrier. Specifically, the FAA is amending the flight prohibition to permit overwater operations in the territory and airspace of Somalia at altitudes below FL260 necessary for climb-outs from, or descents into, Djibouti Ambouli International Airport (HDAM) in the Addis Ababa FIR (HAAA). These operations are subject to the approval of the appropriate authorities of Djibouti and must be conducted in accordance with the conditions established by those authorities and consistent with air traffic control instructions. Operators climbing out of or descending into Djibouti Ambouli International Airport (HDAM) must remain overwater while operating in the territory and airspace of Somalia at altitudes below FL260 and must be either on a published instrument procedure or under the direction of air traffic control. Because weapons systems to which extremist and/or militant groups active in Somalia likely have access have minimal ranges from the coastline, and aircraft using these approaches and departures would only briefly be present in the territory and airspace of Somalia at altitudes below FL260, the FAA determined such operations present a low risk.

However, the FAA has determined increasing safety-of-flight risks exist for U.S. civil aviation operations in the rest of the territory and airspace of Somalia at altitudes below FL260 from extremist and militant activity, as described in the Discussion of the Final Rule section of this preamble. For this reason, the FAA extends the expiration date of this rule from January 7, 2023, until January 7, 2027. Consistent with other recently published flight prohibition SFARs, this action also republishes the approval process and exemption information for this flight prohibition SFAR.

II. Authority and Good Cause

A. Authority

The FAA is responsible for the safety of flight in the U.S. and for the safety of U.S. civil operators, U.S.-registered civil aircraft, and U.S.-certificated airmen throughout the world. Sections 106(f) and (g) of title 49, U.S. Code (U.S.C.), subtitle I, establish the FAA Administrator's authority to issue rules on aviation safety. Subtitle VII of title 49, Aviation Programs, describes in more detail the scope of the agency's authority. Section 40101(d)(1) provides that the Administrator shall consider in the public interest, among other matters, assigning, maintaining, and enhancing safety and security as the highest

priorities in air commerce. Section 40105(b)(1)(A) requires the Administrator to exercise this authority consistently with the obligations of the U.S. Government under international agreements.

The FAA is promulgating this rule under the authority described in 49 U.S.C. 44701, General requirements. Under that section, the FAA is charged broadly with promoting safe flight of civil aircraft in air commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures that the Administrator finds necessary for safety in air commerce and national security.

This regulation is within the scope of the FAA's authority because it continues to prohibit the persons described in paragraph (a) of SFAR No. 107, § 91.1613, from conducting flight operations in the territory and airspace of Somalia at altitudes below FL260 due to the increasing hazards to the safety of U.S. civil flight operations, as described in the preamble to this final rule.

B. Good Cause for Immediate Adoption

Section 553(b)(B) of title 5, U.S. Code, 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.'' Also, section 553(d) permits agencies, upon a finding of good cause, to issue rules with an effective date less than 30 days from the date of publication. In this instance, the FAA finds good cause to forgo notice and comment and the delayed effective date because they would be impracticable and contrary to the public interest.

The risk environment for U.S. civil aviation in airspace managed by other countries with respect to safety of flight is fluid in circumstances involving weapons capable of targeting or otherwise negatively affecting U.S. civil aviation, as well as other hazards to U.S. civil aviation associated with fighting, extremist and militant activity, or periods of heightened tensions. This fluidity and the need for the FAA to rely upon classified information and controlled unclassified information not authorized for public release in assessing these risks make providing notice and opportunity to comment impracticable. The potential for rapid changes in the risks to U.S. civil aviation significantly limits how far in advance of a new or amended flight prohibition the FAA can usefully assess the risk environment. Furthermore, to the extent these rules and any amendments are based upon classified information or controlled unclassified information not authorized for public release, the FAA cannot share such information with the general public. As a result, engaging in notice and comment would be impracticable.

Additionally, it is in the public interest for the FAA's flight prohibitions, and any amendments thereto, to reflect the agency's current understanding of the risk environment for U.S. civil aviation and set appropriate boundaries for the flight prohibition to minimize such risks. This allows the FAA to protect the safety of U.S. operators' aircraft and the lives of their passengers and crews without over-restricting or under-restricting U.S. operators' routing options. The delay that would be occasioned by providing an opportunity to comment on this action would significantly increase the risk that the resulting final action would not accurately reflect the current risks to U.S. civil aviation associated with the situation and thus would not establish boundaries for the flight prohibition commensurate with those risks.

While the FAA sought and responded to public comments, the boundaries of the area in which unacceptable risks to the safety of U.S. civil aviation existed might change due to: evolving military or political circumstances; extremist and militant group activity; the introduction, removal, or repositioning of more advanced anti-aircraft weapons systems; or other factors. As a result, if the situation improved while the FAA sought and responded to public comments, the rule the FAA finalized might be over-restrictive, unnecessarily limiting U.S. operators' routing options and potentially causing them to incur unnecessary additional fuel and operations-related costs, as well as potentially causing passengers to incur unnecessarily some costs attributed to their time. Conversely, if the situation deteriorated while the FAA sought and responded to public comments, the rule the FAA finalized might be under-restrictive, allowing U.S. civil aviation to continue operating in areas where unacceptable risks to their safety had developed. Such an outcome would endanger the safety of these aircraft, as well as their passengers and crews, exposing them to unacceptable risks of death, injury, and property damage that could occur if a U.S. operator's aircraft were shot down (or otherwise damaged) while operating in the territory and airspace of Somalia at altitudes below FL260.

For the reasons previously described, engaging in notice and comment for this rule would be impracticable and contrary to the public interest. Similarly, the potential safety impacts and the need for prompt action on up to date information that is not public would make delaying the effective date impracticable and contrary to the public interest. Accordingly, the FAA finds good cause exists to forgo notice and comment and any delay in the effective date for this rule.

III. Background

When the FAA last extended the rule prohibiting certain U.S. civil flight operations in the territory and airspace of Somalia at altitudes below FL260 in 2019,[1] it assessed that the situation in the territory and airspace of Somalia at altitudes below FL260 remained hazardous for U.S. civil aviation operations due to the poor security environment and fragile governance structure in Somalia, as well as the threat posed by al-Shabaab, an al-Qa'ida-aligned extremist group, and other extremists/militants. Al-Shabaab had demonstrated an intent and capabilities to target civil aviation operations in the territory and airspace of Somalia at altitudes below FL260 through a variety of means, including the use of an insider to smuggle a concealed improvised explosive device (IED) onto a civil aircraft, use of anti-aircraft-capable weapons, and direct and indirect attacks on Somali airports. Al-Shabaab had frequently targeted Aden Adde International Airport (HCMM) with attacks using indirect fire, small-arms fire, and vehicle-borne IEDs.

In addition, al-Shabaab also frequently conducted vehicle-borne IED attacks targeting Western interests and public venues in Mogadishu, including detonating vehicle-borne IEDs near malls (February 2019), hotels (November 2018), and near a security checkpoint close to Aden Adde International Airport (HCMM) (June 2019). Al-Shabaab was also assessed to have access to anti-aircraft-capable weapons presenting a risk to U.S. civil aviation operations at altitudes below FL260. Furthermore, the Islamic State of Iraq and ash-Sham (ISIS) had a cell trying to gain influence in Somalia, which presented another extremist threat to Western interests, including civil aviation. The FAA was concerned ISIS elements in Somalia might have access to anti-aircraft-capable weapons.

In February 2019, the African Union Mission in Somalia (AMISOM) began to draw down its forces, as its mandate was set to expire in 2020, and began

[1] *Extension of the Prohibition Against Certain Flights in the Territory and Airspace of Somalia,* 84 FR 67665, December 11, 2019.

transferring security responsibilities back to Somalia. During the AMISOM drawdown, the FAA assessed that al-Shabaab might attempt to exploit vulnerabilities in Somali security and increase attacks on remaining AMISOM bases and Western interests. For these reasons, the FAA was concerned the risk to U.S. civil aviation operations might increase as AMISOM continued its scheduled drawdown. As a result of the significant continuing risks to the safety of U.S. civil aviation in the territory and airspace of Somalia at altitudes below FL260, the FAA extended the expiration date of SFAR No. 107, § 91.1613, from January 7, 2020 until January 7, 2023.

IV. Discussion of the Final Rule

While developing this final rule, the FAA became aware that certain approaches and departures into and out of Djibouti Ambouli International Airport (HDAM) in the Addis Ababa FIR (HAAA) require flights using those approaches and departures to briefly transit overwater portions of Somalia's territorial airspace [2] at altitudes below FL260. The FAA assessed the flightpaths used to conduct these operations and determined the brief presence of U.S. civil aviation overwater in the territory and airspace of Somalia at altitudes below FL260 necessary to use these approaches and departures would present a low risk. The risks to U.S. civil aviation operations in the territory and airspace of Somalia at altitudes below FL260 from extremist and militant activity are concentrated primarily on and over the land territory of Somalia. Weapons systems to which extremist/militant groups active in Somalia likely have access have minimal ranges from the coastline. Therefore, the FAA is amending SFAR No. 107, § 91.1613, to permit U.S. civil aviation operations to operate overwater in the territory and airspace of Somalia at altitudes below FL260 to the extent necessary to climb out of, or descend into, Djibouti Ambouli International Airport (HDAM) in the Addis Ababa FIR (HAAA). These operations are subject to the approval of the appropriate authorities of Djibouti and must be conducted in accordance with the conditions established by those authorities and consistent with air traffic control instructions. Operators climbing out of or descending into Djibouti Ambouli International Airport (HDAM) must remain overwater while operating in the territory and airspace of Somalia at altitudes below FL260 and must be either on a published instrument procedure or under the direction of air traffic control.

The FAA assesses the situation in the rest of the territory and airspace of Somalia at altitudes below FL260 as being increasingly hazardous for U.S. civil aviation. Since mid-2020, the number, lethality, and complexity of militant and/or extremist attacks has continued to increase, posing increased risk concerns for U.S. civil aviation operations in the territory and airspace of Somalia at altitudes below FL260. The Government of Somalia remains challenged in establishing security and governance in the country amidst economic constraints and faces increased threats from militant and/or extremist groups, particularly al-Shabaab.

Since the December 2019 final rule, AMISOM has reduced its forces in Somalia and continues the process of restructuring its presence into the African Union Transition Mission in Somalia (ATMIS). Al-Shabaab, the primary threat to U.S. civil aviation operations in the territory and airspace of Somalia at altitudes below FL260, has taken advantage of security transitions and drawdowns to expand its influence and attack operations. Al-Shabaab continues to demonstrate its intent and various capabilities to conduct attacks on targets often collocated with airports and against civil aviation. In 2022, al-Shabaab conducted multiple high-profile attacks demonstrating its increasing capacity and capability to conduct complex attacks throughout Somalia.

For example, during the first half of 2022, al-Shabaab frequently targeted international forces and Government of Somalia electoral venues located at Aden Adde International Airport (HCMM) using a variety of capabilities and tactics, including rocket fire, small-arms fire, and IEDs. These attacks often resulted in temporary flight disruptions at Aden Adde International Airport (HCMM). In May 2022, al-Shabaab successfully overran an African Union base at El Baraf, resulting in significant casualties and al-Shabaab's seizure of various weapons, including light anti-aircraft artillery weapon systems. In August 2022, al-Shabaab claimed responsibility for an attack on a hotel complex in Mogadishu frequented by Somali government officials.

Al-Shabaab and ISIS factions operating in Somalia likely have access to a variety of weapons, including man-portable air defense systems (MANPADS), heavy machine guns, rocket-propelled grenades (RPGs), and small-arms. Some MANPADS may be capable of reaching a maximum altitude of 25,000 feet above ground level (AGL), presenting a risk to U.S. civil aviation operations in the territory and airspace of Somalia at altitudes below FL260.

Additionally, al-Shabaab is working to further develop its capabilities, including a weaponized unmanned aircraft systems (UAS) capability. If this effort is successful, it would present further increased safety-of-flight risks to aircraft operating at lower altitudes in the vicinity of potentially targeted airports and airfields and to aircraft on the ground at these locations, both as a collision hazard and as a weapon system. Al-Shabaab has also expanded its weapons procurement efforts and indigenous production of weapons, increasing the quantity of weapons available for use in attacks.

In addition to extremist/militant activity, third-party forces—operating in Somalia without adequate coordination with Somali aviation authorities and a complete air picture present inadvertent risks to U.S. civil aviation operations in the territory and airspace of Somalia at altitudes below FL260. For example, international forces operating in Somalia engaged civil aircraft with small-arms fire on at least two occasions in 2020.

The FAA has determined, based on the enduring risks to U.S. civil aviation operations in the territory and airspace of Somalia at altitudes below FL260 described in this preamble, that four years is an appropriate duration for this SFAR. Therefore, as a result of the increasing unacceptable risk to the safety of U.S. civil aviation operations in the territory and airspace of Somalia at altitudes below FL260, the FAA extends the expiration date of SFAR No. 107, § 91.1613, from January 7, 2023, until January 7, 2027.

Further amendments to SFAR No. 107, § 91.1613, might be appropriate if the risk to U.S. civil aviation safety and security changes. In this regard, the FAA will continue to monitor the situation and evaluate the extent to which persons described in paragraph (a) of this rule might be able to operate safely in the territory and airspace of Somalia at altitudes below FL260.

The FAA also republishes the details concerning the approval and exemption processes in sections V and VI of this preamble, consistent with other recently published flight prohibition SFARs, to enable interested persons to refer to this final rule for comprehensive information about requesting relief from the FAA from the provisions of SFAR No. 107, § 91.1613.

[2] As a general matter, a country's territorial waters extend 12 nautical miles from its coastal baselines determined in accordance with international law, and the airspace above a country's territorial waters forms part of that country's territorial airspace.

V. Approval Process Based on a Request From a Department, Agency, or Instrumentality of the United States Government

A. Approval Process Based on an Authorization Request From a Department, Agency, or Instrumentality of the United States Government

In some instances, U.S. Government departments, agencies, or instrumentalities may need to engage U.S. civil aviation to support their activities in the territory and airspace of Somalia at altitudes below FL260. If a department, agency, or instrumentality of the U.S. Government determines that it has a critical need to engage any person described in paragraph (a) of SFAR No. 107, § 91.1613, including a U.S. air carrier or commercial operator, to transport civilian or military passengers or cargo or conduct other operations in the territory and airspace of Somalia at altitudes below FL260, that department, agency, or instrumentality may request the FAA approve persons described in paragraph (a) of SFAR No. 107, § 91.1613, to conduct such operations.

The requesting U.S. Government department, agency, or instrumentality must submit the request for approval to the FAA's Associate Administrator for Aviation Safety in a letter signed by an appropriate senior official of the requesting department, agency, or instrumentality.[3] The FAA will not accept or consider requests for approval from anyone other than the requesting U.S. Government department, agency, or instrumentality. In addition, the senior official signing the letter requesting FAA approval must be sufficiently positioned within the requesting department, agency, or instrumentality to demonstrate that the organization's senior leadership supports the request for approval and is committed to taking all necessary steps to minimize aviation safety and security risks to the proposed flights. The senior official must also be in a position to: (1) attest to the accuracy of all representations made to the FAA in the request for approval and (2) ensure that any support from the requesting U.S. Government department, agency, or instrumentality described in the request for approval is in fact brought to bear and is maintained over time. Unless justified by exigent circumstances, requesting U.S. Government departments, agencies, or instrumentalities must submit requests for approval to the FAA no less than 30 calendar days before the date on which the requesting department, agency, or instrumentality wishes the operator(s) to commence the proposed operation(s).

The requestor must send the request to the Associate Administrator for Aviation Safety, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591. Electronic submissions are acceptable, and the requesting entity may request that the FAA notify it electronically as to whether the FAA grants the request for approval. If a requestor wishes to make an electronic submission to the FAA, the requestor should contact the Air Transportation Division, Flight Standards Service, at (202) 267–8166, to obtain the appropriate email address. A single letter may request approval from the FAA for multiple persons described in SFAR No. 107, § 91.1613, or for multiple flight operations. To the extent known, the letter must identify the person(s) the requester expects the SFAR to cover on whose behalf the U.S. Government department, agency, or instrumentality seeks FAA approval, and it must describe—

- The proposed operation(s), including the nature of the mission being supported;
- The service the person(s) covered by the SFAR will provide;
- To the extent known, the specific locations in the territory and airspace of Somalia at altitudes below FL260 where the proposed operation(s) will occur, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the territory and airspace of Somalia at altitudes below FL260 and the airports, airfields, or landing zones at which the aircraft will take off and land; and
- The method by which the requesting department, agency, or instrumentality will provide, or how the operator will otherwise obtain, current threat information and an explanation of how the operator will integrate this information into all phases of the proposed operations (*i.e.,* the pre-mission planning and briefing, in-flight, and post-flight phases).

The request for approval must also include a list of operators with whom the U.S. Government department, agency, or instrumentality requesting FAA approval has a current contract(s), grant(s), or cooperative agreement(s) (or its prime contractor has a subcontract(s)) for specific flight operations in the territory and airspace of Somalia at altitudes below FL260. The requestor may identify additional operators to the FAA at any time after the FAA issues its approval. Neither the operators listed in the original request, nor any operators the requestor subsequently seeks to add to the approval, may commence operations under the approval until the FAA issues them an Operations Specification (OpSpec) or Letter of Authorization (LOA), as appropriate, for operations in the territory and airspace of Somalia at altitudes below FL260. The approval conditions discussed below apply to all operators. Requestors should send updated lists to the email address they obtain from the Air Transportation Division by calling (202) 267–8166.

If an approval request includes classified information or controlled unclassified information not authorized for public release, requestors may contact Aviation Safety Inspector Bill Petrak for instructions on submitting it to the FAA. His contact information appears in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

FAA approval of an operation under SFAR No. 107, § 91.1613, does not relieve persons subject to this SFAR of the responsibility to comply with all other applicable FAA rules and regulations. Operators of civil aircraft must comply with the conditions of their certificates, OpSpecs, and LOAs, as applicable. Operators must also comply with all rules and regulations of other U.S. Government departments, agencies, or instrumentalities that may apply to the proposed operation(s), including, but not limited to, regulations issued by the Transportation Security Administration.

B. Approval Conditions

If the FAA approves the request, the FAA's Aviation Safety organization will send an approval letter to the requesting U.S. Government department, agency, or instrumentality informing it that the FAA's approval is subject to all of the following conditions:

(1) The approval will stipulate those procedures and conditions that limit, to the greatest degree possible, the risk to the operator, while still allowing the operator to achieve its operational objectives.

(2) Before any approval takes effect, the operator must submit to the FAA:

(a) A written release of the U.S. Government from all damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising out of or related to the approved operations in the territory and airspace of Somalia at altitudes below FL260, unless climbing

[3] This approval procedure applies to U.S. Government departments, agencies, or instrumentalities; it does not apply to the public. The FAA describes this procedure in the interest of providing transparency with respect to the FAA's process for interacting with U.S. Government departments, agencies, or instrumentalities that seek to engage U.S. civil aviation to operate in the area in which this SFAR would prohibit their operations in the absence of specific FAA approval.

out of or descending into Djibouti Ambouli International Airport while remaining overwater in the territory and airspace of Somalia at altitudes below FL260 and either on a published instrument procedure or under the direction of air traffic control; and

(b) The operator's written agreement to indemnify the U.S. Government with respect to any and all third-party damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising out of or related to the approved operations in the territory and airspace of Somalia at altitudes below FL260, unless climbing out of or descending into Djibouti Ambouli International Airport while remaining overwater in the territory and airspace of Somalia at altitudes below FL260 and either on a published instrument procedure or under the direction of air traffic control.

(3) Other conditions the FAA may specify, including those the FAA might impose in OpSpecs or LOAs, as applicable.

The release and agreement to indemnify do not preclude an operator from raising a claim under an applicable non-premium war risk insurance policy the FAA issues under 49 U.S.C. chapter 443.

If the FAA approves the proposed operation(s), the FAA will issue an OpSpec or LOA, as applicable, to the operator(s) identified in the original request and any operators the requestor subsequently adds to the approval, authorizing them to conduct the approved operation(s). In addition, as stated in paragraph (3) of this section V.B., the FAA notes that it may include additional conditions beyond those contained in the approval letter in any OpSpec or LOA associated with a particular operator operating under this approval, as necessary in the interests of aviation safety. U.S. Government departments, agencies, and instrumentalities requesting FAA approval on behalf of entities with which they have a contract or subcontract, grant, or cooperative agreement should request a copy of the relevant OpSpec or LOA directly from the entity with which they have any of the foregoing types of arrangements, if desired.

VI. Information Regarding Petitions for Exemption

Any operations not conducted under an approval the FAA issues through the approval process set forth previously may only occur in accordance with an exemption from SFAR No. 107, § 91.1613. A petition for exemption must comply with 14 CFR part 11. The FAA will consider whether exceptional circumstances exist beyond those described in the approval process in the previous section. To determine whether a petition for exemption from the prohibition this SFAR establishes fulfills the standard of 14 CFR 11.81, the FAA consistently finds necessary the following information:

- The proposed operation(s), including the nature of the operation;
- The service the person(s) covered by the SFAR will provide;
- The specific locations in the territory and airspace of Somalia at altitudes below FL260 where the proposed operation(s) will occur, including, but not limited to, the flight path and altitude of the aircraft while it is operating in the territory and airspace of Somalia at altitudes below FL260 and the airports, airfields, or landing zones at which the aircraft will take off and land;
- The method by which the operator will obtain current threat information and an explanation of how the operator will integrate this information into all phases of its proposed operations (*i.e.,* the pre-mission planning and briefing, in-flight, and post-flight phases); and
- The plans and procedures the operator will use to minimize the risks identified in this preamble to the proposed operations, to support the relief sought and demonstrate that granting such relief would not adversely affect safety or would provide a level of safety at least equal to that provided by this SFAR. The FAA has found comprehensive, organized plans and procedures of this nature to be helpful in facilitating the agency's safety evaluation of petitions for exemption from flight prohibition SFARs.

The FAA includes, as a condition of each such exemption it issues, a release and agreement to indemnify, as described previously.

The FAA recognizes that, with the support of the U.S. Government, the governments of other countries could plan operations that may be affected by SFAR No. 107, § 91.1613. While the FAA will not permit these operations through the approval process, the FAA will consider exemption requests for such operations on an expedited basis and in accordance with the order of preference set forth in paragraph (c) of SFAR No. 107, § 91.1613.

If a petition for exemption includes information that is sensitive for security reasons or proprietary information, requestors may contact Aviation Safety Inspector Bill Petrak for instructions on submitting it to the FAA. His contact information is listed in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.

VII. Regulatory Notices and Analyses

Federal agencies consider impacts of regulatory actions under a variety of Executive orders and other requirements. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.,* requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 (Pub. L. 96–39), as codified in 19 U.S.C. chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. chapter 25, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

In conducting these analyses, the FAA has determined this final rule has benefits that justify its costs. This rule is a significant regulatory action, as defined in section 3(f) of Executive Order 12866, as it raises novel policy issues contemplated under that Executive order. As 5 U.S.C. 553 does not require notice and comment for this final rule, 5 U.S.C. 603 and 604 do not require regulatory flexibility analyses regarding impacts on small entities. This rule will not create unnecessary obstacles to the foreign commerce of the United States. This rule will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector, by exceeding the threshold identified previously.

A. Regulatory Evaluation

This rule prohibits U.S. civil flights in the territory and airspace of Somalia at altitudes below FL260 due to the significant, increasing risks to the safety of U.S. civil aviation described in this

preamble. The alternative flight routes result in some additional fuel and operations costs to the operators, as well as some costs attributed to passenger time. Accordingly, the incremental costs of the extension of this SFAR are minimal. By continuing to prohibit unsafe flights, the benefits of this rule will exceed the minimal flight deviation costs. Therefore, the FAA finds that the incremental costs of extending SFAR No. 107, § 91.1613, will be minimal and are exceeded by the benefits of avoided risk of deaths, injuries, and property damage that could occur if a U.S. operator's aircraft were shot down (or otherwise damaged) while operating in the territory and airspace of Somalia at altitudes below FL260.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), in 5 U.S.C. 603, requires an agency to prepare an initial regulatory flexibility analysis describing impacts on small entities whenever 5 U.S.C. 553 or any other law requires an agency to publish a general notice of proposed rulemaking for any proposed rule. Similarly, 5 U.S.C. 604 requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553 after that section or any other law requires publication of a general notice of proposed rulemaking. The FAA concludes good cause exists to forgo notice and comment and to not delay the effective date for this rule. As 5 U.S.C. 553 does not require notice and comment in this situation, 5 U.S.C. 603 and 604 similarly do not require regulatory flexibility analyses.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the potential effect of this final rule and determined that its purpose is to protect the safety of U.S. civil aviation from risks to their operations in the territory and airspace of Somalia at altitudes below FL260, a location outside the U.S. Therefore, the rule complies with the Trade Agreements Act of 1979.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million.

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the FAA to consider the impact of paperwork and other information collection burdens it imposes on the public. The FAA has determined no new requirement for information collection is associated with this final rule.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, the FAA's policy is to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined no ICAO Standards and Recommended Practices correspond to this regulation. The FAA finds this action is fully consistent with the obligations under 49 U.S.C. 40105(b)(1)(A) to ensure the FAA exercises its duties consistently with the obligations of the United States under international agreements.

While the FAA's flight prohibition does not apply to foreign air carriers, DOT codeshare authorizations prohibit foreign air carriers from carrying a U.S. codeshare partner's code on a flight segment that operates in airspace for which the FAA has issued a flight prohibition for U.S. civil aviation. In addition, foreign air carriers and other foreign operators may choose to avoid, or be advised or directed by their civil aviation authorities to avoid, airspace for which the FAA has issued a flight prohibition for U.S. civil aviation.

G. Environmental Analysis

The FAA has analyzed this action under Executive Order 12114, Environmental Effects Abroad of Major Federal Actions, and DOT Order 5610.1C, Paragraph 16. Executive Order 12114 requires the FAA to be informed of environmental considerations and take those considerations into account when making decisions on major Federal actions that could have environmental impacts anywhere beyond the borders of the United States. The FAA has determined this action is exempt pursuant to section 2–5(a)(i) of Executive Order 12114 because it does not have the potential for a significant effect on the environment outside the United States.

The FAA has determined that this action will not have a significant environmental effect abroad. In accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 8–6(c), the FAA has prepared a memorandum for the record stating the reason(s) for this determination and has placed it in the docket for this rulemaking.

VIII. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132. The agency has determined this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, this rule will not have federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this rule under Executive Order 13211. The agency has determined it is not a ''significant energy action'' under the Executive order and will not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609 promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive

Order 13609 and has determined that this action will have no effect on international regulatory cooperation.

IX. Additional Information

A. Electronic Access

Except for classified and controlled unclassified material not authorized for public release, all documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the docket for this rulemaking.

Those documents may be viewed online at *https://www.regulations.gov* using the docket number listed above. A copy of this rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *https://www.federalregister.gov* and the Government Publishing Office's website at *https://www.govinfo.gov.* A copy may also be found at the FAA's Regulations and Policies website at *https://www.faa.gov/regulations_policies.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or notice number of this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121) (set forth as a note to 5 U.S.C. 601) requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the persons listed under the **FOR FURTHER INFORMATION CONTACT** section at the beginning of the preamble. To find out more about SBREFA on the internet, visit *https://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Freight, Somalia.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations, as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1613 by revising paragraphs (c) and (e) to read as follows:

§ 91.1613 Special Federal Aviation Regulation No. 107—Prohibition Against Certain Flights in the Territory and Airspace of Somalia.

* * * * *

(c) *Permitted operations.* This section does not prohibit persons described in paragraph (a) of this section from conducting flight operations in the territory and airspace of Somalia under the following circumstances:

(1) Overflights of Somalia may be conducted at altitudes at or above FL260 subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Somalia.

(2) Aircraft departing from Djibouti Ambouli International Airport (International Civil Aviation Organization (ICAO) code: HDAM) may operate overwater in the territory and airspace of Somalia at altitudes below FL260 only to the extent necessary to permit a climb during takeoff if the operator of that aircraft:

(i) Receives any necessary approval from the appropriate authorities of Djibouti;

(ii) Conducts operations that comply with applicable conditions established by the appropriate authorities of Djibouti and air traffic control instructions; and

(iii) Is either on a published instrument procedure or under the direction of air traffic control.

(3) Aircraft descending into Djibouti Ambouli International Airport (HDAM) may operate overwater at altitudes below FL260 in the territory and airspace of Somalia only to the extent necessary to permit descent for landing at Djibouti Ambouli International Airport (HDAM), if the operator of that aircraft:

(i) Receives any necessary approval from the appropriate authorities of Djibouti;

(ii) Conducts operations that comply with applicable conditions established by the appropriate authorities of Djibouti and air traffic control instructions; and

(iii) Is either on a published instrument procedure or under the direction of air traffic control.

(4) Flight operations may be conducted in the territory and airspace of Somalia at altitudes below FL260 if such flight operations are conducted under a contract, grant, or cooperative agreement with a department, agency, or instrumentality of the U.S. Government (or under a subcontract between the prime contractor of the U.S. Government department, agency, or instrumentality and the person described in paragraph (a) of this section) with the approval of the FAA or under an exemption issued by the FAA. The FAA will consider requests for approval or exemption in a timely manner, with the order of preference being: First, for those operations in support of U.S. Government-sponsored activities; second, for those operations in support of government-sponsored activities of a foreign country with the support of a U.S. Government department, agency, or instrumentality; and third, for all other operations.

* * * * *

(e) *Expiration.* This SFAR will remain in effect until January 7, 2027. The FAA may amend, rescind, or extend this SFAR, as necessary.

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f) and (g), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5).

Billy Nolen,

Acting Administrator.

[FR Doc. 2022–28134 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

Construction Related Relief Concerning Operations at Ronald Reagan Washington National Airport, John F. Kennedy International Airport, and LaGuardia Airport, and Newark Liberty International Airport, April 1, 2023, Through November 30, 2023

AGENCY: Federal Aviation Administration (FAA), Department of Transportation.

ACTION: Notification of limited waiver of the slot usage requirement.

SUMMARY: This action grants a limited, conditional waiver of the minimum slot usage requirements at Ronald Reagan Washington National Airport (DCA) due

to runway construction and closures at the airport in 2023 and for impacted flights between DCA and slot-controlled airports John F. Kennedy International Airport (JFK) and LaGuardia Airport (LGA). In addition, the FAA will provide similar limited, conditional relief at Newark Liberty International Airport (EWR) under the FAA's Level 2 schedule facilitation process.

DATES: The usage waiver and policies in this notification are effective on December 27, 2022 and apply from April 1, 2023, through November 30, 2023.

ADDRESSES: Requests may be submitted by mail to the Slot Administration Office, System Operations Services, AJR–0, Room 300W, 800 Independence Avenue SW, Washington, DC 20591, or by email to: *7-awa-slotadmin@faa.gov.*

FOR FURTHER INFORMATION CONTACT: For questions concerning this notification contact: Al Meilus, Slot Administration and Capacity Analysis, FAA ATO System Operations Services, AJR–G5, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone 202–264–0568; email *al.meilus@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Metropolitan Washington Airports Authority (MWAA) plans airfield and runway construction at DCA beginning in 2023 and continuing into 2024. The main Runway 1–19 will be closed nightly from approximately May 1, 2023, through October 15, 2023, from 11:00 p.m. to 5:59 a.m. Eastern Time on weekdays and potentially on weekends depending on the construction project's progress. Runway 4–22 will be closed nightly and open for Runway 4 daytime departures only for the duration of the construction project. Runway 15–33 will have nightly closures in late April 2023 and again in mid-June to late July 2023, including the intersection with Runway 1–19. Associated taxiways will also be rehabilitated during the project.

The FAA limits the number of arrivals and departures at DCA through the implementation of the High Density Rule (HDR).[1] The HDR hourly limits at DCA are 37 air carrier slots, 11 commuter slots, and 12 reservations available for other operations.[2] The ''Other'' class of users is limited to unscheduled operations such as general aviation, charters, military, and non-passenger flights and is not intended for scheduled flight or other regularly conducted commercial operations. The FAA limits the number of arrivals and departures at JFK and LGA by FAA Order.[3]

At DCA, JFK, and LGA, each slot must be used a minimum of 80 percent of the time.[4] At DCA and LGA, any slot not used at least 80 percent of the time over a two-month period will be recalled by the FAA.[5] At JFK, usage is calculated seasonally, slots not meeting the minimum usage requirement will not receive historic status for the following equivalent scheduling season.[6] The FAA may waive the 80 percent minimum usage requirement if a highly unusual and unpredictable condition beyond the control of the slot-holding air carrier affects carrier operations for a period of five consecutive days or more at JFK and LGA and nine consecutive days or more at DCA.[7]

The FAA designated EWR a Level 2 airport under the Worldwide Slot Guidelines (WSG), now known as the Worldwide Airport Slot Guidelines (WASG). The FAA does not allocate slots, apply historic precedence, or impose minimum usage requirements at EWR. Level 2 schedule facilitation depends upon close and continuous discussions and voluntary agreement between airlines and the FAA to reduce congestion. At Level 2 airports, the FAA generally provides priority consideration for flights approved by the FAA and operated by the carrier in those approved times in the prior scheduling season when the FAA reviews proposed flights for facilitation in the next corresponding scheduling season. However, the FAA notes that the usual Level 2 processes include flexibility for the facilitator to prioritize planned flights, which are canceled in advance or on the day of the scheduled operation due to operational impacts that are beyond the control of the carrier.

Summary of Petitions Received

On November 30, 2022, Airlines for America (A4A) filed a petition on behalf of member and associate member airlines requesting a limited waiver of the minimum slot usage rules at DCA due to the impending runway construction. The petition also sought either a limited waiver of the minimum slot usage requirements or schedule relief at LGA, EWR, and JFK for slots or movements for nonstop flights to and from DCA during specified hours. A4A states that ''construction at DCA will impose conditions that will significantly impact operations and those conditions are beyond the control of the slot holders, thereby providing good cause for the requested waiver.'' A4A indicates ''the nighttime closing of the main Runway 1–19 will significantly impact carriers that hold slots in the 2300 hour by forcing them to use Runway 15–33 or not operate.'' A4A notes that ''for many carriers, the option to use 15–33 will have a negative impact because some aircraft, such as the 737–900/ER/MAX are unable to use runway 15–33'' and ''other aircraft will need to apply hefty payload penalties to operate on runway 15–33, for example some aircraft would need to reduce between 50 and 75 passengers on all but the shortest routes.''

A4A also requests relief for slot pairs associated with the 2300–0559 closure period, noting carriers may seek alleviation for the closures slot's pair, which may be outside the 2300–0600 hours and requests the FAA ''work with carriers on an individual basis to determine their slot pairing needs and requests as carriers' monthly schedules develop.''

In addition, A4A requests relief for slot usage associated with several operations between DCA and JFK, EWR, or LGA. Specifically, A4A requests the FAA grant slot usage or schedule alleviation to ''departure slots between 2100 and 2200 used for nonstop service to DCA, as such flights typically arrive at DCA in the 2300 hour'' and ''for any DCA departure slots between 0500 and 0659 used for nonstop service to those slot-controlled or schedule facilitated New York airports.''

Southwest Airlines Co. (Southwest) filed a request for temporary slot flexibility at DCA on December 5, 2022. Specifically, Southwest requests that the FAA permit Southwest to move three flights currently scheduled in the 2300

[1] 33 FR 17896 (Dec. 3, 1968). The FAA codified the rules for operating at high-density traffic airports in 14 CFR part 93, subpart K. The HDR requires carriers to hold a reservation, known as a ''slot,'' for each takeoff or landing under instrument flight rules at the high-density traffic airports. Currently, only operations at DCA are limited by the HDR.

[2] 14 CFR 93.123.

[3] Operating Limitations at John F. Kennedy International Airport. 73 FR 3510 (Jan. 18, 2008), as amended, and most recently extended by 87 FR 65161 (Oct. 28, 2022). Operating Limitations at New York LaGuardia Airport. 71 FR 77854 (Dec. 27, 2006), as amended, and most recently extended by 87 FR 65159 (Oct. 28, 2022).

[4] Operating Limitations at John F. Kennedy International Airport, 87 FR 65161 at 65162 (Oct. 28, 2022); Operating Limitations at New York LaGuardia Airport, 87 FR 65159 at 65160 (Oct. 28, 2022); 14 CFR 93.227(a).

[5] Operating Limitations at New York LaGuardia Airport, 87 FR 65159 at 65160 (Oct. 28, 2022); 14 CFR 93.227(a).

[6] Operating Limitations at John F. Kennedy International Airport, 87 FR 65161 at 65162 (Oct. 28, 2022).

[7] Operating Limitations at John F. Kennedy International Airport, 87 FR 65161 at 65163 (Oct. 28, 2022); Operating Limitations at New York LaGuardia Airport, 87 FR 65159 at 65160 (Oct. 28, 2022); 14 CFR 93.227(j).

hour to available hours earlier in the day rather than canceling the flights during the DCA construction and closure periods. Southwest does not oppose the waiver request filed by A4A but ''believes that FAA should pursue the goal of enabling carriers to maintain all possible capacity at DCA to promote competition, maintain low fares, and ensure nonstop travel options for the flying public.'' Southwest states there is available capacity in other hours for Southwest to move its flights without exceeding hours limits based on 60 operations per hour.[8]

FAA Analysis and Decision

The FAA has determined the DCA airport construction and runway closures warrant limited, conditional relief from the minimum slot usage requirements because the impacts to operations in certain hours are beyond the carriers' control and will exist for several months. The closures from 2300–0559 Eastern Time are expected to impact operations as described by A4A and Southwest.

DCA is a high-demand airport, and carriers have indicated they plan to operate flights if feasible. There are typically 15 to 16 arrivals in the 2300 hour with the corresponding aircraft used for departures in the morning hours with additional potential for a few cancellations in the late evening hours and the corresponding departures. The FAA is not limiting the relief to certain hours in order to provide some degree of flexibility to carriers to allow them to balance schedules and slot pairs. However, the FAA may require carriers to justify how returned slots are impacted by the runway closure if returned slots are not during or adjacent to the runway closure periods.

The FAA will work individually with carriers on retiming and schedule adjustment options; however, the FAA will not retime air carrier operations into hours that are currently at the air carrier slot limit. The FAA notes that carriers at DCA regularly engage in swapping slots for retiming purposes or in temporary leasing of slots and those options remain available for carriers to manage slot holdings at the airport.

In addition, the FAA is extending a limited, conditional waiver from minimum usage requirements at JFK and LGA and providing similar relief at EWR under the Level 2 process for departure slots or approved schedules between 2100 and 2200 used for nonstop service to DCA, as well as slots or approved schedules associated with a DCA departure between 0500 and 0659 used for nonstop service to those slot-controlled or schedule facilitated New York City area airports. Carriers may also choose to use those slots at JFK and LGA or the approved runway times at EWR for operations to other markets than DCA.

The FAA will treat as used the specific slots impacted by the construction for the period from April 1, 2023, through November 30, 2023. This provides some time before and after the currently planned runway closure dates to accommodate potential changes to the construction schedule and provide carriers that may need some relief on either side of the current anticipated construction dates to phase in or phase out current operations. The relief is subject to the following conditions:

1. The specific slots must be returned to the FAA at least four weeks prior to the date of the FAA-approved operation, by submission to *7-awa-slotadmin@faa.gov.*

2. Slots newly allocated after December 1, 2022, for initial use before November 30, 2023, are not eligible for relief.

3. Slots authorized at DCA by Department of Transportation or FAA exemptions are not eligible for relief.

4. At JFK, LGA, and EWR only departure slots or approved schedules between 2100 and 2200 used for nonstop service to DCA and slots or approved schedules associated with a DCA departure between 0500 and 0659 used for nonstop service to those slot-controlled or schedule facilitated New York City area airport are eligible for relief.

Issued in Washington, DC.

Marc A. Nichols,

Chief Counsel.

Alyce Hood-Fleming,

Vice President, System Operations Services.

[FR Doc. 2022–27967 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

[8] The High Density Rule hourly limits for DCA are 37 air carrier slots, 11 commuter slots, and 12 reservations available for Other operations. The Other category is limited to unscheduled operations such as general aviation, charters, military, and non-passenger flights and is not intended for scheduled flight or other regularly conducted commercial operations.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31463; Amdt. No. 4039]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 27, 2022. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 27, 2022.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The applicable FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers or aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the type of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for Part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

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

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on December 9, 2022.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 26 January 2023

Winchester, IN, I22, RNAV (GPS) RWY 26, Amdt 1A
Kill Devil Hills, NC, KFFA, RNAV (GPS) RWY 3, Orig-A
Kill Devil Hills, NC, KFFA, RNAV (GPS) RWY 21, Orig-A

Effective 23 February 2023

Sitka, AK, PASI, VOR/DME–A, Amdt 1, CANCELED
Auburn, AL, KAUO, VOR–A, Amdt 8B, CANCELED
Phoenix, AZ, KDVT, DEER VALLEY TWO, Graphic DP
Phoenix, AZ, KDVT, Takeoff Minimums and Obstacle DP, Amdt 7
San Jose, CA, KSJC, RNAV (GPS) Y RWY 30L, Amdt 4A
San Jose, CA, KSJC, RNAV (GPS) Y RWY 30R, Amdt 4B
Denver, CO, KAPA, ILS OR LOC RWY 35R, Amdt 11B
Denver, CO, KAPA, RNAV (GPS) RWY 17L, Amdt 2A
Denver, CO, KAPA, RNAV (GPS) RWY 35R, Amdt 1B
Ocala, FL, KOCF, ILS OR LOC RWY 36, Amdt 2
Ocala, FL, KOCF, VOR RWY 36, Amdt 19
Gainesville, GA, KGVL, ILS OR LOC RWY 5, Amdt 1
Gainesville, GA, KGVL, RNAV (GPS) RWY 5, Amdt 2
Gainesville, GA, KGVL, RNAV (GPS) RWY 23, Amdt 2
Jasper, GA, KJZP, RNAV (GPS) RWY 16, Amdt 2
Atlantic, IA, KAIO, RNAV (GPS) RWY 20, Amdt 1D
Harlan, IA, KHNR, RNAV (GPS) RWY 15, Amdt 1

Rock Rapids, IA, KRRQ, RNAV (GPS) RWY 34, Amdt 1B
Anthony, KS, KANY, RNAV (GPS) RWY 18, Amdt 2A
Hugoton, KS, KHQG, RNAV (GPS) RWY 20, Orig-C
Marysville, KS, KMYZ, RNAV (GPS) RWY 16, Orig-C
Washington, KS, K38, RNAV (GPS) RWY 17, Amdt 1C
Murray, KY, KCEY, LOC RWY 23, Amdt 2C, CANCELED
Augusta, ME, KAUG, RNAV (GPS) RWY 8, Amdt 2, CANCELED
Augusta, ME, KAUG, Takeoff Minimums and Obstacle DP, Amdt 5
Allegan, MI, 35D, RNAV (GPS) RWY 11, Orig-D
Allegan, MI, 35D, RNAV (GPS) RWY 29, Orig-C
Three Rivers, MI, KHAI, VOR–A, Amdt 10A, CANCELED
Fairmont, MN, KFRM, RNAV (GPS) RWY 13, Orig-C
Rush City, MN, KROS, NDB RWY 34, Orig-B, CANCELED
Windom, MN, KMWM, RNAV (GPS) RWY 35, Amdt 1C
Worthington, MN, KOTG, RNAV (GPS) RWY 11, Amdt 1A
Worthington, MN, KOTG, RNAV (GPS) RWY 18, Amdt 1A
Farmington, MO, KFAM, RNAV (GPS) RWY 2, Amdt 1A
Natchez, MS, KHEZ, Takeoff Minimums and Obstacle DP, Orig-A
Liberty, NC, 2A5, RNAV (GPS) RWY 2, Orig-C, CANCELED
Liberty, NC, 2A5, RNAV (GPS) RWY 20, Orig-B, CANCELED
Liberty, NC, 2A5, Takeoff Minimums and Obstacle DP, Amdt 1, CANCELED
Omaha, NE, KOMA, RNAV (GPS) Y RWY 36, Amdt 2A
Newark, NJ, KEWR, GLS RWY 22L, Amdt 1
Newark, NJ, KEWR, GLS RWY 22R, Amdt 2
Deming, NM, KDMN, Takeoff Minimums and Obstacle DP, Amdt 3
Deming, NM, KDMN, VOR RWY 26, Amdt 10B, CANCELED
Deming, NM, KDMN, VOR–B, Orig
Jackson, OH, KJRO, RNAV (GPS) RWY 19, Amdt 1F
Lancaster, SC, KLKR, NDB RWY 24, Amdt 5, CANCELED
Burnet, TX, KBMQ, RNAV (GPS) RWY 1, Orig-F
Burnet, TX, KBMQ, RNAV (GPS) RWY 19, Orig-E
Burnet, TX, KBMQ, Takeoff Minimums and Obstacle DP, Amdt 2A
Mesquite, TX, KHQZ, ILS OR LOC RWY 18, Amdt 1D, CANCELED
Mesquite, TX, KHQZ, LOC/DME BC RWY 36, Amdt 4, CANCELED
Mineola/Quitman, TX, KJDD, RNAV (GPS) RWY 18, Orig-E
Paris, TX, KPRX, VOR RWY 35, Amdt 2C
Stratford, TX, H70, Takeoff Minimums and Obstacle DP, Amdt 4A, CANCELED
Milwaukee, WI, KMKE, RNAV (GPS) RWY 7L, Amdt 1A

Rescinded: On November 25, 2022 (87 FR 72383), the FAA published an Amendment in Docket No. 31456, Amdt No. 4033, to Part 97 of the Federal Aviation Regulations under section 97.33. The following entries for, Tulsa, OK, effective December 29, 2022, is hereby rescinded in its entirety:

Tulsa, OK, KTUL, RNAV (GPS) RWY 36L, Amdt 1A

[FR Doc. 2022–28112 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31464; Amdt. No. 4040]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 27, 2022. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 27, 2022.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff

Minimums and ODPs as identified in the amendatory language for Part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

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

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on December 9, 2022.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
26–Jan–23	MA	Southbridge	Southbridge Muni	2/5388	11/21/22	RNAV (GPS) RWY 2, Orig-C.
26–Jan–23	IA	Council Bluffs	Council Bluffs Muni	2/6420	11/18/22	Takeoff Minimums and Obstacle DP, Amdt 1.
26–Jan–23	FL	New Smyrna Beach	New Smyrna Beach Muni.	2/6973	11/29/22	RNAV (GPS) RWY 7, Orig-B.
26–Jan–23	FL	New Smyrna Beach	New Smyrna Beach Muni.	2/6974	11/29/22	RNAV (GPS) RWY 2, Orig-B.
26–Jan–23	FL	New Smyrna Beach	New Smyrna Beach Muni.	2/6975	11/29/22	RNAV (GPS) RWY 29, Orig-B.
26–Jan–23	FL	New Smyrna Beach	New Smyrna Beach Muni.	2/6976	11/29/22	RNAV (GPS) RWY 25, Orig-B.
26–Jan–23	NE	Wahoo	Wahoo Muni	2/8111	11/30/22	RNAV (GPS) RWY 20, Orig.
26–Jan–23	PA	Waynesburg	Greene County	2/8243	11/28/22	RNAV (GPS) RWY 27, Orig-B.
26–Jan–23	PA	Waynesburg	Greene County	2/8244	11/28/22	RNAV (GPS) Z RWY 9, Amdt 1.

[FR Doc. 2022–28111 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2021–N–0851]

Medical Devices; Immunology and Microbiology Devices; Classification of the Human Leukocyte Antigen Typing Companion Diagnostic Test

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

ACTION: Final amendment; final order.

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

DATES: This order is effective December 27, 2022. The classification was applicable on November 28, 2022.

FOR FURTHER INFORMATION CONTACT: Karen Fikes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 72, Rm. 7301, Silver Spring, MD, 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the human leukocyte antigen typing companion diagnostic test as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

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

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

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

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

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

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

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

II. De Novo Classification

On July 1, 2022, One Lambda, Inc., submitted a request for De Novo classification of the SeCORE CDx HLA Sequencing System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

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

Therefore, on November 28, 2022, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 866.5960.[1] We have named the generic type of device human leukocyte antigen typing companion diagnostic test, and it is identified as a prescription genotyping or phenotyping in vitro diagnostic product intended for use as an aid in identifying patients who have specific human leukocyte antigen (HLA) allele(s) or express specific HLA antigen(s) and may benefit from treatment with a corresponding therapeutic product or are likely to be at increased risk for serious adverse

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

reactions as a result of treatment with a corresponding therapeutic product.

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

TABLE 1—HUMAN LEUKOCYTE ANTIGEN TYPING COMPANION DIAGNOSTIC TEST RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Inaccurate test results (false positive or false negative results) can result in adverse health consequences.	Labeling, design verification and validation, clinical validity data, bridging study.
Failure of software to correctly interpret test results can result in adverse health consequences.	Software verification and validation.

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

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

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

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

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

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

■ 2. Add § 866.5960 to subpart F to read as follows:

§ 866.5960 Human leukocyte antigen typing companion diagnostic test.

(a) *Identification.* A human leukocyte antigen (HLA) typing companion diagnostic (CDx) test is a prescription genotyping or phenotyping in vitro diagnostic product intended for use as an aid in identifying patients who have specific HLA allele(s) or express specific HLA antigen(s) and may benefit from treatment with a corresponding therapeutic product or are likely to be at increased risk for serious adverse reactions as a result of treatment with a corresponding therapeutic product.

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

(1) The intended use of the device must specify the target HLA allele(s) or antigen(s), the patient population(s), and the corresponding therapeutic product(s).

(2) Design verification and validation must include:

(i) Detailed documentation of an analytical accuracy study that uses well-characterized samples including clinical samples from intended use population(s) focusing on the target allele(s) needed for patient selection;

(ii) Detailed documentation of precision studies (repeatability, reproducibility) that evaluate possible sources of variation that may affect test results;

(iii) Detailed documentation of a study determining range of input sample concentrations that meet performance specifications;

(iv) Detailed description of the ambiguity resolution method, if applicable;

(v) For a sequencing-based assay, documentation of coverage and predefined coverage threshold of target genomic regions, pertinent variant types, and sequence contexts;

(vi) For multiplex assays, documentation of a risk assessment and design specifications that are in place to prevent incorrect reactivity assignment;

(vii) Description of a plan on how to ensure the performance of the device does not change when new HLA alleles are identified, and/or when reactivity assignments are changed; and

(viii) Detailed description of device software including standalone software, or software and bioinformatics analysis pipeline, if applicable, incorporated in the instruments, and documentation of software including the level of concern and associated risks, software requirement specifications, software design specifications (*e.g.,* algorithms, alarms and device limitations), hazard analysis, traceability matrix, verification and validation testing, unresolved anomalies, hardware requirements, and effective cybersecurity management.

(3) Clinical validity data (which may include summary reports from clinical trials, comparison studies using clinical samples, or through an alternative approach determined to be appropriate by FDA), demonstrating the following, as applicable:

(i) Which patients identified by the HLA CDx test are most likely to benefit from the corresponding therapeutic product; and

(ii) Which patients identified by the HLA CDx test are likely to be at increased risk for serious adverse reactions as a result of treatment with the corresponding therapeutic product.

(4) If the HLA test used in the clinical trials is different from the HLA CDx test

in the premarket notification submission, the submission must include results of a bridging study, or an alternative approach determined to be appropriate by FDA.

Dated: December 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28035 Filed 12–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2022–N–3130]

Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Hemodynamic Indicator With Decision Point

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

ACTION: Final amendment; final order.

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

DATES: This order is effective December 27, 2022. The classification was applicable on March 1, 2021.

FOR FURTHER INFORMATION CONTACT: Shawn Forrest, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2224, Silver Spring, MD 20993–0002, 301–796–5554, *Shawn.Forrest@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the adjunctive hemodynamic indicator with decision point as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

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

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

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

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

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

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

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

II. De Novo Classification

On April 3, 2020, FDA received Fifth Eye Inc.'s request for De Novo classification of the Analytic for Hemodynamic Instability. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

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

Therefore, on March 1, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding

21 CFR 870.2220.[1] We have named the generic type of device adjunctive hemodynamic indicator with decision point, and it is identified as a device that identifies and monitors hemodynamic condition(s) of interest and provides notifications at a clinically meaningful decision point. This device is intended to be used adjunctively along with other monitoring and patient information.

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

TABLE 1—ADJUNCTIVE HEMODYNAMIC INDICATOR WITH DECISION POINT RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Delayed or incorrect treatment due to erroneous output as a result of software malfunction or algorithm error.	Software verification, validation, and hazard analysis; Non-clinical performance testing; Clinical data; and Labeling.
Delayed or incorrect treatment due to user misinterpretation	Usability assessment, and Labeling.

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

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo Classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

Medical devices.

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

PART 870—CARDIOVASCULAR DEVICES

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

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

■ 2. Add § 870.2220 to subpart C to read as follows:

§ 870.2220 Adjunctive hemodynamic indicator with decision point.

(a) *Identification.* An adjunctive hemodynamic indicator with decision point is a device that identifies and monitors hemodynamic condition(s) of interest and provides notifications at a clinically meaningful decision point. This device is intended to be used adjunctively along with other monitoring and patient information.

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

(1) Software description, verification, and validation based on comprehensive hazard analysis and risk assessment must be provided, including:

(i) Full characterization of technical parameters of the software, including algorithm(s);

(ii) Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications;

(iii) Specification of acceptable incoming sensor data quality control measures;

(iv) Mitigation of impact of user error or failure of any subsystem components (signal detection and analysis, data display, and storage) on output accuracy; and

(v) The sensitivity, specificity, positive predictive value, and negative predictive value in both percentage and number form for clinically meaningful pre-specified time windows consistent with the device output.

(2) Scientific justification for the validity of the hemodynamic indicator algorithm(s) must be provided. Verification of algorithm calculations and validation testing of the algorithm must use an independent data set.

(3) Usability assessment must be provided to demonstrate that risk of misinterpretation of the status indicator is appropriately mitigated.

(4) Clinical data must support the intended use and include the following:

(i) The assessment must include a summary of the clinical data used, including source, patient demographics, and any techniques used for annotating and separating the data;

(ii) Output measure(s) must be compared to an acceptable reference method to demonstrate that the output represents the measure(s) that the device provides in an accurate and reproducible manner;

(iii) The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified;

(iv) Where continuous measurement variables are displayed, agreement of the output with the reference measure(s)

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

must be assessed across the full measurement range; and

(v) Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output and be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment.

(5) Labeling must include the following:

(i) The type of sensor data used, including specification of compatible sensors for data acquisition, and a clear description of what the device measures and outputs to the user;

(ii) Warnings identifying factors that may impact output results;

(iii) Guidance for interpretation of the outputs, including warning(s) specifying adjunctive use of the measurements;

(iv) Key assumptions made in the calculation and determination of measurements; and

(v) A summary of the clinical validation data, including details of the patient population studied (*e.g.,* age, gender, race/ethnicity), clinical study protocols, and device performance with confidence intervals for all intended use populations.

Dated: December 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28131 Filed 12–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Russian Harmful Foreign Activities Sanctions Regulations Determination

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of a determination.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing a price cap determination issued pursuant to an April 6, 2022 Executive order. The determination was previously issued on OFAC's website.

DATES: The Determination Pursuant to Sections l(a)(ii), l(b), and 5 of Executive Order 14071 was issued on December 5, 2022.

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

SUPPLEMENTARY INFORMATION:

Electronic Availability

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

Background

On December 5, 2022, the Secretary of the Treasury, in consultation with the Secretary of State, issued a determination pursuant to sections l(a)(ii), l(b), and 5 of Executive Order 14071 to impose a price cap on crude oil of Russian origin. The determination took effect at 12:01 a.m. eastern standard time on December 5, 2022, and was published on OFAC's website (*www.treas.gov/ofac*) on December 5, 2022. The text of the determination is below.

Determination Pursant to Sections 1(a)(ii), 1(b), and 5 of Executive Order 14071

Price Cap on Crude Oil of Russian Federation Origin

Pursuant to sections l(a)(ii), l(b), and 5 of Executive Order (E.O.) 14071 of April 6, 2022 (''Prohibiting New Investment in and Certain Services to the Russian Federation in Response to Continued Russian Federation Aggression''), and the determination on November 21, 2022 made pursuant to sections l(a)(ii), l(b), and 5 of E.O. 14071 (''Prohibitions on Certain Services as They Relate to the Maritime Transport of Crude Oil of Russian Federation Origin''), the Secretary of the Treasury, in consultation with the Secretary of State, hereby determines that, effective 12:01 a.m. eastern standard time on December 5, 2022, the price cap on crude oil of Russian Federation origin shall be $60 per barrel.

Janet L. Yellen,

Secretary, U.S. Department of the Treasury.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–28153 Filed 12–23–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2021–0336]

RIN 1625–AA09

Drawbridge Operation Regulation; Fox River, Oshkosh, WI

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending the operating schedule that governs the Tayco Street Bridge, mile 37.52, the Main Street Bridge, mile 55.97, the Jackson Street Bridge, mile 56.22, the Wisconsin Street Bridge, mile 56.72, and the Congress Avenue Bridge, mile 58.01, all over the Fox River near Oshkosh, Wisconsin. This rule will allow the bridges to operate remotely and will not change the operating schedule of the bridge. The Wisconsin Department of Transportation (WisDOT) requested the change.

DATES: This rule is effective January 26, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type the docket number USCG–2021–0336 in the ''SEARCH'' box and click ''SEARCH''. In the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, email *Lee.D.Soule@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
§ Section
U.S.C. United States Code
WisDOT Wisconsin Department of Transportation

II. Background Information and Regulatory History

On July 6, 2021, we published a notice of temporary deviation from regulations and request for comments in the **Federal Register** (86 FR 35402). Weaccepted comments until November 1, 2021. This deviation allowed mariners to experience the proposed regulation and comment about the

operations of the bridges. We received nine comments that we addressed and incorporated into the NPRM that we published in the **Federal Register** (87 FR 18751) on March 31, 2022. We solicited comments on the NPRM until May 31, 2022, and we did not receive any additional comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499.

The Main Street Bridge, mile 55.97, provides a horizontal clearance of 89 feet and a vertical clearance of 11 feet in the closed position, the Jackson Street Bridge, mile 56.22, provides a horizontal clearance of 97 feet and a vertical clearance of 11 feet in the closed position, the Wisconsin Street Bridge, mile 56.72, provides a horizontal clearance of 75 feet and a vertical clearance of 12 feet in the closed position, the Congress Avenue Bridge, mile 58.01, provides a horizontal clearance of 75 feet and a vertical clearance of 13 feet in the closed position, and the Tayco Street Bridge provides a horizontal clearance of 63 feet and a vertical clearance of 3 feet in the closed position. All of these bridges are over the Fox River and provide an unlimited clearance in the open position, and are governed by the regulations found in 33 CFR 117.1087.

The WisDOT requested to operate these bridges remotely and this required an update to the CFR and a sufficient public comment period on the bridge operations before any changes were made. This will not change the schedule of the bridges.

Because this rule will not change the bridge schedule or the movement of vehicles over the bridges, vehicle counts were not consulted.

Approximately 100 powered and unpowered recreational vessels pass through these bridges every day during the summer. Commercial salvage and construction vessels use the waterway in limited numbers.

IV. Discussion of Comments, Changes and the Final Rule

During the Test Deviation, we provided a comment period of 180 days and received 9 comments that were used to develop and publish the NPRM; the NPRM provided an additional 60 days for the public to comment. We did not receive any additional comments pursuant to the NPRM.

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.

A. Regulatory Planning and Review

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

There will be no burden to any mode of transportation. The only change is the bridges will operate remotely.

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 did not receive any comments 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.

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** section.

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

C. Collection of Information

This rule 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.

We did not receive any comments from any Indian Tribal Governments.

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. We did not receive any comments from State, local, or tribal governments.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy 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). The Coast Guard has 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 and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table3–1 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.

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. Amend § 117.1087 by adding paragraph (b)(3) to read as follows:

§ 117.1087 Fox River.

* * * * *

(b) * * *

(3) All drawbridges between mile 37.52 and 58.01, are authorized to be operated remotely, and are required to operate and maintain a VHF–FM Marine Radio.

* * * * *

M.J. Johnston,

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

[FR Doc. 2022–28130 Filed 12–23–22; 8:45 am]

BILLING CODE 9110–04–P

Proposed Rules

Federal Register
Vol. 87, No. 247
Tuesday, December 27, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2020–0036]

RIN 3150–AK71

Reporting Requirements for Nonemergency Events at Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory basis; extension of comment period.

SUMMARY: On November 9, 2022, the U.S. Nuclear Regulatory Commission (NRC) requested comments on a regulatory basis to support a rulemaking that would amend its regulations for nonemergency event notifications. The public comment period was originally scheduled to close on January 9, 2023. The NRC is extending the comment period to allow more time for members of the public to develop and submit their comments.

DATES: The due date of comments requested in the document published on November 9, 2022 (87 FR 67571), is extended. Comments should be filed no later than January 31, 2023. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0036. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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.

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: Alexa Sieracki, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–301–7509; email: *Alexa.Sieracki@nrc.gov;* or Brian Benney, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2767; email: *Brian.Benney@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0036 (formerly Docket ID NRC–2018–0201) for the associated petition for rulemaking) 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–2020–0036 (or Docket ID NRC–2018–0201 for the associated petition for rulemaking).
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0036 in your comment submission.

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 will post all comment submissions at *https://www.regulations.gov* as well as enter 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 submission. 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 into ADAMS.

II. Discussion

On November 9, 2022, the NRC requested comments on a regulatory basis to support a rulemaking that would amend its regulations for nonemergency event notifications, evaluate the current requirements and guidance for immediate notification of nonemergency events for operating nuclear power reactors and assess whether the requirements present an unnecessary reporting burden.

The public comment period was originally scheduled to close on January 9. 2023. The NRC has decided to extend the public comment period on this document until January 31, 2023, to allow more time for members of the public to submit their comments.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking

website at *https://www.regulations.gov* under Docket ID NRC–2020–0036. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2020–0036); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

Dated: December 19, 2022.

For the Nuclear Regulatory Commission.

Christopher M. Regan,

Director, Division of Rulemaking, Environmental, and Financial Support Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2022–27979 Filed 12–23–22; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1654; Project Identifier MCAI–2022–01165–T]

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–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. This proposed AD was prompted by reports of some passenger oxygen mask dispensing units (MDUs) with lanyards that are too long to meet the proper length specifications of the airplane. This proposed AD would require replacing the affected MDUs with units that meet the proper length specifications, replacing the placards, and re-identifying the assemblies. 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 February 10, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1654; 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 mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this NPRM, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com*.
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Elizabeth M. Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–361–8046; 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 **ADDRESSES**. Include ''Docket No. FAA–2022–1654; Project Identifier MCAI–2022–01165–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Elizabeth M. Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–361–8046; email *9-avs-nyaco-cos@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.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2022–50, dated August 25, 2022 (also referred to after this as the MCAI), to correct an unsafe condition on certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. The MCAI states that lanyards of passenger mask dispensing units installed in the affected airplanes are too long to meet the proper length specifications of the aircraft. This condition, if not corrected, could result in the inability to initiate the flow of oxygen to the mask when required in an emergency situation, with no indication to the passenger that they are not receiving oxygen.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1654.

Related Service Information Under 1 CFR Part 51

Bombardier has issued the following service information, which describes procedures for identifying part numbers of the drop-down oxygen boxes, performing drop-down oxygen mask

reach testing, marking failed seats as inoperative with placards, and replacing affected oxygen masks:

- Service Bulletin 600–0777, dated December 13, 2021.
- Service Bulletin 601–1109, Revision 01, dated May 6, 2022.
- Service Bulletin 604–35–007, Revision 01, dated May 6, 2022.

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

These products are approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

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

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 301 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
1 work-hour × $85 per hour = $85	$0	$85	$25,585

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
2 work-hours × $85 per hour = $170	$100	$270

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) Would not affect intrastate aviation in Alaska, and

(3) Would 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:

Bombardier, Inc.: Docket No. FAA–2022–1654; Project Identifier MCAI–2022–01165–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by February 10, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., airplanes, certificated in any category, with serial numbers as identified in the service information specified in paragraphs (c)(1) through (4) of this AD.

(1) Model CL–600–1A11 (600) airplanes: Bombardier Service Bulletin 600–0777, dated December 13, 2021.

(2) Model CL–600–2A12 (601) airplanes: Bombardier Service Bulletin 601–1109, Revision 01, dated May 6, 2022.

(3) Model CL–600–2B16 (601–3A, 601–3R) airplanes: Bombardier Service Bulletin 601–1109, Revision 01, dated May 6, 2022.

(4) Model CL–600–2B16 (604) airplanes: Bombardier Service Bulletin 604–35–007, Revision 01, dated May 6, 2022.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen System.

(e) Unsafe Condition

This AD was prompted by reports of passenger oxygen mask dispensing units installed in the affected airplanes with lanyards that are too long to meet the proper length specifications of the airplane. The FAA is issuing this AD to address the inability to initiate flow of oxygen to the mask. The unsafe condition, if not addressed, could result in no indication to the passenger that they are not receiving oxygen in an emergency situation.

(f) Compliance

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

(g) Inspection and Replacement

Within 5 years after the effective date of this AD, determine the part number of the drop-down oxygen box, in accordance with Section 2.B. of the Accomplishment Instructions of the applicable service information identified in paragraphs (c)(1) through (4) of this AD.

(1) If any drop-down oxygen box part number (P/N) installed on the airplane matches any P/N listed in Table 1 of Section 2.B. of the applicable service information: Before further flight, perform drop-down oxygen mask reach testing in accordance with Section 2.B.(2) of the Accomplishment Instructions of the applicable service information identified in paragraphs (c)(1) through (4) of this AD.

(i) If the test result is PASS: Before further flight, replace the drop-down oxygen box assembly in accordance with Section 2.C., and test the passenger oxygen supply system in accordance with Section 2.D.(2), of the applicable service information identified in paragraphs (c)(1) through (4) of this AD.

(ii) If the test result is FAIL for any individual seat: Before further flight, mark the failed seat as inoperative in accordance with Section 2.B.(3) of the applicable service information specified in paragraphs (c)(1) through (4) of this AD.

(2) If the part number of any drop-down oxygen box assembly installed on the airplane is not found in Table 1 of Section 2.B. of the applicable service information identified in paragraphs (c)(1) through (4) of this AD: Before further flight, do actions to correct the unsafe condition using a method approved in accordance with the procedures specified in paragraph (i)(1) of this AD.

(h) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 601–1109, dated December 13, 2021; or Bombardier Service Bulletin 604–35–007, dated December 13, 2021; as applicable.

(i) Additional 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 responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the New York ACO Branch, mail it to ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (j)(2) of this AD or email to: *9-avs-nyaco-cos@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards 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; or Bombardier, Inc.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

(1) Refer to Transport Canada AD CF–2022–50, dated August 25, 2022, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1654.

(2) For more information about this AD, contact Elizabeth M. Dowling, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–361–8046; email *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 600–0777, dated December 13, 2022.

(ii) Bombardier Service Bulletin 601–1109, Revision 01, dated May 6, 2022.

(iii) Bombardier Service Bulletin 604–35–007, Revision 01, dated May 6, 2022.

(3) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

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

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

Issued on December 20, 2022.

Christina Underwood,

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

[FR Doc. 2022–28063 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0727; FRL–10421–01–R4]

Air Plan Approval; Kentucky; Revision to Federally Enforceable District Origin Operating Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Jefferson County portion of the Kentucky State Implementation Plan (SIP) submitted by the Commonwealth of Kentucky through the Kentucky Energy and Environment Cabinet (Cabinet) on June 15, 2022. The changes were submitted by the Cabinet on behalf of the Louisville Metro Air Pollution Control District (District, also referred to herein as Jefferson County). The District's revision modifies the permit application timing requirements in the Federally Enforceable District Origin Operating Permits (FEDOOP) rule in the Jefferson County portion of the Kentucky SIP (Jefferson County Local Implementation Plan, or LIP). EPA is proposing to approve these changes pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before January 26, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2022–0727 at *regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to

make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, 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.*

FOR FURTHER INFORMATION CONTACT: Pearlene Williams-Miles, 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. The telephone number is (404) 562–9144. Ms. Williams-Miles can also be reached via electronic mail at *williamsmiles.pearlene@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Overview

On June 15, 2022, the Commonwealth of Kentucky submitted changes to the Jefferson County LIP for EPA approval.[1] [2] EPA is proposing to approve changes to Section 4—*Permit Applications,* of the District's Regulation 2.17—*Federally Enforceable District Origin Operating Permits.*[3] Under Regulation 2.17, Section 1.1, a FEDOOP is an operating permit that contains a federally enforceable condition, limit, or provision that is issued to a stationary source that is not, or would not subsequently be, required to obtain a permit under Regulation 2.16—*Title V Operating Permits.* The changes in the June 15, 2022, submission add timing requirements for sources applying for FEDOOP permits that are similar to those in Regulation 2.16—Section II of the preamble of this document provides EPA's analysis and rationale for proposed approval of this revision.

II. Analysis of Kentucky's SIP Revision

The June 15, 2022, submission revises Regulation 2.17 by adding four timing requirements under Section 4—*Permit Applications,* adding new prefatory language in Section 4.2, and renumbering the remaining subsections within Section 4. Turning to the four new timing requirements, first, subsection 4.2.1 is added to require that sources not previously required to obtain a permit under Regulation 2.17 but that become subject to an applicable requirement after the effective date of the regulation must submit a permit application within 12 months from the time at which it became subject to Regulation 2.17.

Second, subsection 4.2.2 is added to require that a source ''constructing, reconstructing, or modifying,'' shall submit a complete FEDOOP permit application within 12 months after commencing operation. If an existing permit would prohibit construction or a change in operation, the source would be required to obtain a permit revision before commencing operation.

Third, subsection 4.2.3 is added to state that a source that is required to reopen an existing permit pursuant to the requirements of Section 6 of Regulation 2.17 must submit a complete application for a permit revision within six months after notification by the District that the permit must be reopened.

Finally, subsection 4.2.4 is added to require that a complete permit application must be submitted to the District at least six months prior to the date of permit expiration and in accordance with Section 6 of Regulation 2.17 for permit renewal.

These changes to Regulation 2.17 merely add timing requirements for submitting complete FEDOOP applications similar to the timing requirements in Regulation 2.16. As such, EPA has preliminarily determined that these changes do not interfere with any applicable requirement concerning attainment of the national ambient air quality standards and reasonable further progress or any other applicable requirement of the Act. For these reasons, EPA is proposing to approve the changes to the Jefferson County LIP.

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, and as described in Section II of this preamble, EPA is proposing to incorporate by reference Jefferson County's Regulation 2.17—*Federally Enforceable District Origin Operating Permits,* version 5, with a local-effective date of March 16, 2022, which adds timing requirements to the permit application process. 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).

IV. Proposed Action

EPA is proposing to approve the aforementioned changes to Regulation 2.17—*Federally Enforceable District Origin Operating Permits,* with a local-effective date of March 16, 2022, into the Jefferson County LIP. EPA is proposing to approve these changes because they are consistent with the CAA.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the 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 they meet the criteria of the CAA. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National

[1] The EPA received this submission on June 13, 2022, in a letter dated June 15, 2022. Throughout this notice of proposed rulemaking, this submission will be referred to as the June 15, 2022, submission.

[2] In 2003, the City of Louisville and Jefferson County governments merged, and the ''Jefferson County Air Pollution Control District'' was renamed the ''Louisville Metro Air Pollution Control District.'' However, to be consistent with the terminology used in the subheading in Table 2 of 40 CFR 52.920(c), throughout this notice we refer to regulations contained in the Jefferson County portion of the Kentucky SIP as the ''Jefferson County'' regulations.

[3] The June 15, 2022, submittal contains changes to other Kentucky SIP-approved rules that are not addressed in this notice. EPA will act on those rules in separate actions.

Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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 proposed 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.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides, Volatile organic compounds.

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

Dated: December 20, 2022.

Daniel Blackmon,

Regional Administrator, Region 4.

[FR Doc. 2022–28147 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 4

[PS Docket Nos. 21–346; 15–80; ET Docket No. 04–35; DA 22–1343; FR ID 119958]

Resilient Networks; Disruptions to Communications

AGENCY: Federal Communications Commission.

ACTION: Petition for clarification and partial reconsideration; extension of filing replies to oppositions.

SUMMARY: In this document, the Federal Communications Commission (Commission) extends the deadline for filing replies to oppositions to the October 31, 2022 Petition for Clarification and Partial Reconsideration (Petition) filed in the above-captioned proceeding.

DATES: The deadline for filing replies to oppositions in response to the Petition is extended to January 10, 2023.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Saswat Misra of the Public Safety and Homeland Security Bureau, Cybersecurity and Communications Reliability Division, at (202) 418–0944 or *Saswat.Misra@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order Granting Extension of Time (*Order*) in PS Docket Nos. 21–346 and 15–80 and ET Docket No. 04–35; DA 22–1343, adopted and released on December 19, 2022. For the full text of this document, visit FCC's website at *https://www.fcc.gov/document/pshsb-extends-opposition-reply-deadline-resiliency-proceeding* or obtain access via the FCC's Electronic Comment Filing System (ECFS) website at *http://www.fcc.gov/ecfs.* (Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.) Alternative formats are available for people with disabilities (braille, large print, electronic files, audio format), by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

I. Synopsis

1. By this *Order,* the Public Safety and Homeland Security Bureau (PSHSB) grants a joint request filed by the Competitive Carriers Association (CCA) and CTIA (collectively, Requestors) seeking an extension of 14 days to file Replies to Oppositions in connection with their Petition for Clarification and Partial Reconsideration (Petition) filed in the above-captioned proceeding. *See* CCA and CTIA Joint Request for Extension of Time to Reply to Oppositions to Petition For Reconsideration, PS Docket Nos. 21–346 and 15–80, ET Docket No. 04–35 (filed Dec. 7, 2022) (Request). For the reasons stated below, PSHSB finds that Requestors' request is warranted, and accordingly extends the deadline for filing Replies to Oppositions to January 10, 2023.

2. On June 27, 2022, the Federal Communications Commission (Commission) adopted a Report and Order addressing improvements to communications reliability during disasters. *See* Resilient Networks; Amendments to Part 4 of the Commission's Rules Concerning Disruptions to Communications; New Part 4 of the Commission's Rules Concerns Disruptions to Communications, PS Docket Nos. 21–346 and 15–80; ET Docket No. 04–35, Report and Order and Further Notice of Proposed Rulemaking (Report and Order), 87 FR 59329 (Sept. 30, 2022). Requestors filed their Petition on October 31, 2022. *See* CTIA and Competitive Carriers Association Petition for Clarification and Partial Reconsideration, PS Docket Nos. 21–346 and 15–80; ET Docket No. 04–35 (filed Oct. 31, 2022).

3. On December 2, 2022, the Office of the Federal Register published notice of the Petition in the **Federal Register** indicating that Oppositions to the Petition would be due on December 19, 2022 and Replies to Oppositions would be due on December 27, 2022. *See* 87 FR 74102 (Dec. 2, 2022); *see also* Public Safety and Homeland Security Bureau Announces Filing Deadlines for Oppositions and Opposition Replies to the Petition for Clarification and Partial Reconsideration filed by CTIA and CCA Regarding the Resilient Networks Report and Order, PS Docket Nos. 21–346 and 15–80; ET Docket No. 04–35, Public Notice (PSHSB Dec. 2, 2022); 47 CFR 1.429(f) and (g).

4. On December 7, 2022, Requestors filed the Request seeking a 14-day extension of the deadline for Replies to Oppositions, from December 27, 2022 to January 10, 2023. In doing so, Requestors note that the current schedule provides only eight days, rather than the typical 10 days, between the filing deadlines for Oppositions and Replies to the Oppositions and that the December 26, 2022 federal holiday for Christmas also falls within this time window. Requestors state that the deadline for Replies to Oppositions should be extended to provide sufficient time for Requestors and other parties to ''review the record, prepare potential oppositions in this complex proceeding, and develop a complete record for the Commission's consideration.'' Requestors further remark that the current schedule ''creates significant challenges to the parties' ability to review any oppositions, formulate positions with constituents and member companies, and draft replies that substantively respond to the oppositions to the Petition.'' Requestors contend that the requested extension would be consistent with past instances where the Commission has granted extensions of time. No objections to the Request have been filed.

5. As set forth in § 1.46 of the Commission's rules, the Commission does not routinely grant extensions of time for such filings. In this case, however, the requested extension is unopposed, limited to only 14 days, and will allow commenters sufficient time to

file meaningful comments given the intervening weekend and Christmas holiday. *See* 47 CFR 1.46; *see also* 47 CFR 1.45(e), 47 CFR 1.3. We therefore grant Requestors unopposed Request and set the new deadline for filing Oppositions to Replies to January 10, 2023. The deadline for filing Oppositions remains December 19, 2022.

II. Ordering Clauses

6. Accordingly, *it is ordered* that, pursuant to section 4(i) and (j) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and (j), and §§ 0.204, 0.392, and 1.46 of the Commission's rules, 47 CFR 0.204, 0.392, 1.46, the Request for Extension of Time filed by Requestors is granted.

7. *It is further ordered* that the date to file Oppositions to Replies in response to the Petition *is extended* to January 10, 2023.

Federal Communications Commission.

Lauren Kravetz,

Chief of Staff, Public Safety and Homeland Security Bureau.

[FR Doc. 2022–28069 Filed 12–23–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Part 1548

[Docket No. TSA–2020–0002]

RIN 1652–AA72

Frequency of Renewal Cycle for Indirect Air Carrier Security Programs

AGENCY: Transportation Security Administration, DHS.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Transportation Security Administration (TSA) is proposing to modify its regulations to reduce the frequency of renewal applications by indirect air carriers (IACs). Rather than requiring these entities to submit an application to renew their security program each year, TSA is proposing to require renewal once every three years. This modification would reduce the burden of compliance without a negative impact on security and would support this industry's economic recovery from the impacts of the COVID–19 public health crisis.

DATES: Submit comments on or before February 27, 2023.

ADDRESSES: You may submit comments, identified by the TSA docket number to this rulemaking, to the Federal Docket Management System (FDMS), a government-wide, electronic docket management system. To avoid duplication, please use only one of the following methods:

- *Electronic Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. The Department of Transportation (DOT), which maintains and processes TSA's official regulatory dockets, will scan the submission and post it to FDMS. Comments must be postmarked by the dates indicated above.
- *Fax:* (202) 493–2251.

See **SUPPLEMENTARY INFORMATION** for format and other information about comment submissions.

FOR FURTHER INFORMATION CONTACT: Angel Rodriguez, telephone 1–571–227–2108; email *angel.l.rodriguez@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

TSA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. You may submit comments, identified by the TSA docket number for this rulemaking, to the **ADDRESSES** noted above. With each comment, please include this docket number at the beginning of your comments. You may submit comments and material electronically, in person, by mail, or fax as provided under **ADDRESSES**, but please submit your comments and material by only one means. If you submit comments by mail or in person submit them in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing.

If you would like TSA to acknowledge receipt of comments submitted by mail, include with your comments a self-addressed, stamped postcard on which the docket number appears. TSA will stamp the date on the postcard and mail it to you.

All comments, except those that include confidential or sensitive security information (SSI) [1] will be posted to *https://www.regulations.gov,* and will include any personal information you have provided. Should you wish your personally identifiable information redacted prior to filing in the docket, please clearly indicate this request in your submission. TSA will consider all comments that are in the docket on or before the closing date for comments and will consider comments filed late to the extent practicable. The docket is available for public inspection before and after the comment closing date.

Handling of Confidential or Proprietary Information and SSI Submitted in Public Comments

Do not submit comments that include trade secrets, confidential commercial or financial information, or SSI to the public regulatory docket. Comments containing this type of information should be submitted separately from other comments, appropriately marked as containing such information, and submitted by mail to the address listed in **FOR FURTHER INFORMATION CONTACT** section. TSA will take the following actions for all submissions containing SSI:

- TSA will not place comments containing SSI in the public docket and will handle them in accordance with applicable safeguards and restrictions on access.
- TSA will hold documents containing SSI, confidential business information, or trade secrets in a separate file to which the public does not have access, and place a note in the public docket explaining that commenters have submitted such documents.
- TSA may include a redacted version of the comment in the public docket.
- TSA will treat requests to examine or copy information that is not in the public docket as any other request under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the Department of Homeland Security (DHS) FOIA regulation found in 6 CFR part 5.

Reviewing Comments in the Docket

Please be aware that anyone is able to search the electronic form of all comments in any of our dockets by the name of the individual who submitted or signed the comment (*e.g.,* if submitted by an association, business, labor union, *etc.*). For more about privacy and the docket, review the Privacy and Security Notice for the

[1] ''Sensitive Security Information'' or ''SSI'' is information obtained or developed in the conduct of security activities, the disclosure of which would constitute an unwarranted invasion of privacy, reveal trade secrets or privileged or confidential information, or be detrimental to the security of transportation. The protection of SSI is governed by 49 CFR part 1520.

FDMS at *https://www.regulations.gov/privacy-notice,* as well as the System of Records Notice DOT/ALL 14—Federal Docket Management System (73 FR 3316, January 17, 2008) and the System of Records Notice DHS/ALL 044—eRulemaking (85 FR 14226, March 11, 2020).

You can review TSA's electronic public docket at *https://www.regulations.gov.* In addition, DOT's Docket Management Facility provides a physical facility, staff, equipment, and assistance to the public. To obtain assistance or to review comments in TSA's public docket, you may visit this facility between 9 a.m. and 5 p.m., Monday through Friday, excluding legal holidays, or call (202) 366–9826. This DOT facility is located in the West Building Ground Floor, Room W12–140 at 1200 New Jersey Avenue SE, Washington, DC 20590.

You can find an electronic copy of rulemaking documents relevant to this action by searching the electronic FDMS web page at *https://www.regulations.gov* or at *https://www.federalregister.gov.* In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section. Make sure to identify the docket number of this NPRM.

Abbreviations and Terms Used in This Document

CCSF—Certified Cargo Screening Facility
CEQ—Council on Environmental Quality
DHS—Department of Homeland Security
DOT—Department of Transportation
E.O.—Executive Order
FOIA—Freedom of Information Act
IAC—Indirect Air Carrier
IACSSP—Indirect Air Carrier Standard Security Program
NEPA—National Environmental Policy Act
OMB—Office of Management and Budget
PRA—Paperwork Reduction Act of 1995
SBREFA—Small Business Regulatory Enforcement Fairness Act of 1996
SSI—Sensitive Security Information
TSA—Transportation Security Administration

I. Executive Summary

A. Purpose of the Regulatory Action

An IAC, sometimes called a freight forwarder, acts as an intermediary between a shipper of air cargo and an air carrier by receiving and consolidating cargo from one or more shippers for transport on one or more aircraft flights. IACs are a critical component of a secure, air cargo supply-chain in the United States, helping to ensure the safe, timely, and efficient movement of goods every day. Approximately 3,800 IACs are operating in the United States and registered with TSA, ranging from sole proprietors working out of their homes to large corporations.

Currently, TSA's regulations require IACs to renew their registration each year. TSA is proposing to modify 49 CFR 1548.7 to reduce the frequency at which IACs must renew their registration from annual to once every three years. This modification will reduce the burden of compliance by decreasing the time and effort an IAC must devote to renewing their registration, permitting them to focus on other operational and business priorities, including meeting supply chain demands as the industry recovers from the impact of the COVID–19 public health crisis.

TSA has determined this modification reduces the cost of compliance without any negative impacts on security. As noted below, TSA estimates that over ten years, cost savings aggregate to $7.8 million undiscounted, $6.6 million discounted at 3 percent, and $5.4 million discounted at 7 percent. The rulemaking would realize an annualized $800,000 in cost savings discounted at 7 percent over 10 years.

II. Background

A. Regulation of IACs

As noted above, IACs play a critical role in ensuring a secure, air cargo supply-chain, acting as an intermediary between the shipper and the aircraft operator.[2] To ensure the security of the air cargo system, TSA imposes security requirements on IACs in 49 CFR part 1548. Through these regulations, TSA ensures ''IACs are held accountable for securing the goods entrusted to them throughout those legs of the supply chain for which they are responsible.'' [3]

Under 49 CFR 1548.5, each IAC must adopt and carry out the IAC Standard Security Program (IACSSP). Persons interested in becoming IACs are vetted by TSA and are required to implement security requirements in the IACSSP. These requirements are intended to ensure security during the period between when a package leaves a shipper and when it is presented to the aircraft operators. IACs must also ensure their employees understand and are trained to implement their security responsibilities.

TSA uses a web-based, centralized system for businesses to obtain IAC approval and to renew this approval. Through this process, TSA checks whether an applicant is a legitimate business and determines whether the business or its personnel pose a threat to transportation security. TSA may withdraw approval of an IAC if individuals or companies are found to be security risks during revalidation.

B. Requirement for Annual Renewal

Current 49 CFR 1548.7(b) presents the processes an IAC must follow annually to seek renewed approval from TSA to operate under the IACSSP. In general, annual renewal is a continuation of current practices and security measures in the IACSSP, including any TSA-approved amendments issued under 49 CFR 1548.7(c), (d), and/or (e). IACs must submit the renewal request to TSA at least 30 calendar days prior to expiration of the IACSSP, as well as other standards for the submission.

Since 2006, TSA has required IACs to renew their registration each year. This requirement was based on the following considerations. First, other entities regulated by a TSA security program, such as aircraft operators and airports, must obtain annual FAA certification, which involves the submission and verification of information relating to the entity and its operations. IACs are not required to do so. Second, TSA found that the IAC industry has a high degree of turnover. The current regulations require the IAC to certify that it has provided TSA with its most up-to-date information and to acknowledge that intentional falsification of the information may be subject to civil and criminal penalties.[4]

Since the annual renewal requirement was imposed in 2006, TSA has determined that it is unnecessary to continue requiring annual renewal and that the program could be renewed once every three years without having a negative impact on security. As discussed below, this determination is based on two key factors: (1) TSA's inspection processes and priorities for IACs negate the need for annual renewals, and (2) the triennial renewal requirement for other TSA air cargo programs that have proven to be effective and secure.

[2] TSA's regulations define an IAC as ''any person or entity within the United States not in possession of [a Federal Aviation Administration] air carrier operating certificate, that undertakes to engage indirectly in air transportation of property, and uses for all or any part of such transportation the services of an air carrier.'' *See* 49 CFR 1540.5. The scope includes businesses engaged in the indirect transport of cargo on larger commercial aircraft, regardless of whether the operation is conducted with a passenger aircraft or an all-cargo aircraft.

[3] *See* Proposed Rule, Air Cargo Security Requirements, 69 FR 65257, 65269 (Nov. 10, 2004).

[4] *See* Air Cargo Security Requirements; Final Rule, 71 FR 30477, 30514 (May 26, 2006).

First, when the annual renewal requirement was imposed in 2006,[5] TSA expected that the annual cycle of renewals would be the primary method to ensure the agency regularly reviewed each IAC and confirmed compliance with TSA security requirements.[6] TSA, however, actually ensures compliance with the program through regular inspections of IACs. IACs are typically subject to a comprehensive inspection on a one, two, or three-year cycle depending on TSA's assessment of the relative security risk for each individual IAC. This security risk determination reflects vulnerabilities that exist based on the results of prior compliance reviews. For example, TSA generally conducts more frequent inspections of IACs that have lower compliance rates in order to ensure the IACs being inspected are performing all actions necessary to provide the required level of security. These reviews include targeted and supplemental inspections.

An additional safeguard is provided by 49 CFR 1540.301, which allows TSA to withdraw approval of an IAC security program if TSA determines continued operation is contrary to security and the public interest.[7] If TSA withdraws approval, an IAC must discontinue operation immediately, regardless of the renewal date of its program certification. *See* discussion in Section III.A. of this NPRM.

Second, in addition to recognizing the effectiveness of its regular inspections to ensure compliance with the IAC program, TSA also considered the requirements for the IAC program compared to other aviation security requirements, specifically requirements applicable to Certified Cargo Screening Facilities (CCSFs) under 49 CFR part 1549. When TSA finalized the rule establishing the Certified Cargo Screening Program in 2011,[8] TSA provided a three-year renewal period for CCSFs.[9] Over more than a decade of implementing the Certified Cargo Screening Program validates that the triennial recertification cycle does not have a negative impact on security. The proposed rule does not change the required actions that IACs must perform to recertify or the requirements they must meet to maintain approval to operate as an IAC; the proposed rule simply reduces the frequency with which they must recertify.

C. Benefits of Proposed Modification of Renewal Period

Consistent with the principles of Executive Order (E.O.) 12866 of September 30, 1993 (Regulatory Planning and Review) and E.O. 13563 of January 18, 2011 (Improving Regulation and Regulatory Review), TSA is committed to ensuring its regulations do not impose more stringent or burdensome requirements than are necessary to provide the intended security benefits. This action is also consistent with the burden-reduction principles of E.O. 14058 of December 13, 2021 (Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government). Whether imposing or revising a regulation, TSA is required by 49 U.S.C. 114(l)(3) to consider, as one factor in a final determination, whether the costs of the regulation are excessive in relation to the enhancement of security the regulation will provide.

TSA has determined that the security benefits of annual recertifications do not outweigh the cost of annual renewal applications. As noted below, TSA estimates that over ten years the cost savings aggregate to $7.8 million undiscounted, $6.6 million discounted at 3 percent, and $5.4 million discounted at 7 percent. The rule would realize annualized savings of $0.8 million in 2020 dollars discounted at 7 percent.

This change in the renewal requirement would not have a negative impact on security as the security enhancements provided by annual recertifications are minimal for the following two reasons. First, IACs are required to notify TSA within 30 days if there are any changes to the information provided in their application. *See* 49 CFR 1548.7(a)(5). This requirement ensures that TSA always has current information regarding the IAC. Second, and as previously noted, TSA's existing inspection program for IACs ensures that those IACs that might be at risk of losing certification are inspected more frequently to ensure they are meeting minimal program requirements. TSA would continue to perform compliance inspections with the same frequency as the current program operation and prioritization. The present inspection schedule, the requirements for inspections, and the scope of required inspections are not modified by this action.

D. Impact of COVID–19 Public Health Crisis on Air Cargo Supply Chain

The current COVID–19 public health crisis has disrupted critical supply chains globally, including throughout the United States. IACs are challenged by the combination of increased demand for air cargo shipments and limitations resulting from the impact of COVID–19 on personnel. As a result, many IACs are facing logistical, operational, and personnel challenges. While the change to the rule may not have a significant economic impact, TSA believes it is appropriate to provide relief from regulatory requirements during this time, enabling IACs to focus their time and effort on the essential tasks of delivering essential goods and services.

III. Summary of the Proposed Rule

TSA is proposing to make limited amendments to the text of paragraphs (a) and (b) in 49 CFR 1548.7, to change the periodic renewal of all IAC security programs from one year to three years. As noted in section I, this modification will reduce the burden of compliance by reducing the time and effort an IAC must devote to renewing their registration, permitting them to focus on other operational and business priorities, including meeting supply chain demands as the industry recovers from the COVID–19 public health crisis. The net result of these changes is a three-year renewal period for the approval to operate as an IAC under the IACSSP.

A. Duration of Program

Currently, 49 CFR 1548.7(a)(4) states that a program remains effective from the time it is approved until the end of the calendar month one year after the month it was approved. The proposed rule removes the words ''one year after the month it was approved'' in paragraph (a)(4) and adds in their place: ''three years after the month it was approved, or until the program has been surrendered or withdrawn, whichever is earlier''.

In addition to the specific change in the renewal period in this section, TSA is proposing to add ''or until the program has been surrendered or withdrawn, whichever is earlier'', to the duration language to ensure greater consistency across TSA's cargo programs.[10] The process for becoming an IAC can be seen as analogous, in some respects, to an enforceable contractual relationship between TSA

[5] *Id.* at 30495. *See also* Proposed Rule, Air Cargo Security Requirements, 69 FR 65257, 65269 (Nov. 10, 2004).

[6] *See supra* n. 4.

[7] *See* 49 CFR 1548.7(f) and 1540.301(b).

[8] *See* Final Rule, Air Cargo Screening, 76 FR 51847 (Aug. 18, 2011).

[9] *See* 49 CFR 1549.7(b).

[10] *See, e.g.,* text relating to Certified Cargo Screening Program renewal periods in 49 CFR 1549.7(a)(6).

and the regulated entity. We grant persons permission to operate as an IAC on condition that they agree to comply with TSA's requirements. There are three actions that could result in a person no longer being able to represent themselves as an IAC: (1) the IAC fails to renew the program by the required deadline;[11] (2) the IAC informs TSA that it no longer intends to function as a TSA-approved IAC (*i.e.,* the IAC surrenders approval to operate as an IAC, similar to the concept of surrender of approval in other TSA programs); or (3) TSA withdraws approval consistent with the standards and procedures in TSA's regulations.[12] The implementation of the changes proposed in this rule would increase the consistency and clarity of regulatory requirements across TSA's air cargo security regulations.[13] TSA is proposing similar changes for paragraph (b)(4), which addresses duration of an IAC's program after renewal.

B. Changes in Information

Paragraph (a)(5) includes the requirement for IACs to notify TSA if any of the information relevant to TSA's approval of the program changes. In this section, TSA is proposing to make clear that the rule covers changes made both after submission of the initial application and information submitted as part of the renewal application. This additional language would clarify TSA's intent and ensure TSA has current information about the IAC's operations that could affect security and the IAC's approval to operate under the IACSSP.

C. Conforming Changes

Under § 1548.7(b)(1), IAC's must submit their application for renewal at least 30 calendar days ''prior to the first day of the anniversary month of initial approval.'' TSA is proposing to revise this language to conform with the proposed three-year duration of the program by requiring applications for renewal to be submitted 30 calendar days prior to the 36th month after the initial approval of its security program.

IV. Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires TSA to comply with small entity requests for information and advice about compliance with statutes and regulations within TSA's jurisdiction. Any small entity that has a question regarding this document may contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Persons can obtain further information regarding SBREFA on the Small Business Administration's web page at *https://www.sba.gov/category/advocacy-navigation-structure/regulatory-policy/regulatory-flexibility-act/sbrefa.*

V. Regulatory Analyses

TSA considered numerous statutes and Executive orders related to rulemaking when developing this rule. The following summarizes TSA's analyses of the impact of the rulemaking as directed by these statutes or Executive orders.

A. Regulatory Planning and Review

1. Background

E.O. 12866 of September 30, 1993 (Regulatory Planning and Review), and E.O. 13563 of January 18, 2011 (Improving Regulation and Regulatory Review), direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

In conducting these analyses, TSA provides the following conclusions and summary information:

- The Office of Management and Budget (OMB) has determined that this rulemaking is not a ''significant regulatory action'' as defined in E.O. 12866; and
- TSA has certified that this rulemaking would not have a significant impact on a substantial number of small entities.

The basis for these conclusions is set forth below.

This proposed rule would reduce regulatory costs by reducing the frequency that IACs must renew their security program certifications. This rule would reduce the frequency of annual IAC security program certifications to once every three years. This rule does not impose any incremental costs because regulated entities are already performing all actions required to obtain the certification in question. The expected outcome will be a minimal impact with positive net benefits.

2. Estimated Cost Savings to Affected Entities

The cost savings from this rule arise from extending the duration of IAC security programs approved by TSA from one year to three years. This change aligns the duration of the IAC security program with the Certified Cargo Screening Program.[14] Table 1 summarizes the change and impact from this action.

TABLE 1—COMPARISON OF CURRENT 49 CFR PART 1548 AND PROPOSED RULE

Current	Proposed rule	Impact	Estimated cost savings
Requires annual renewal of security program.	Revises to renewal every three years.	(1) Aligns part 1548 renewal period with that of the TSA-approved Certified Cargo Screening Program, part 1549. (2) Provides cost savings to industry and TSA.	TSA estimates the annualized cost saving to industry and Federal government to be $800,000 annualized at a 7 percent discount rate. Cost savings arise from time saved due to a less frequent security program renewal cycle.

To estimate cost savings, TSA calculates the number of instances an IAC would resubmit a security program under the current annual requirement, and the number of instances that would be avoided under the proposed rule's three-year requirement. TSA uses the difference in the number of resubmission instances between the current requirement and the proposed rule as the basis for the cost savings.

TSA uses historical data on the number of existing IACs to forecast the number of security programs submitted for certification over the ten-year period of analysis. TSA assumes that the regulatory change for less frequent recertification does not impact the annual number of forecasted active IAC certifications. Based on historical program data, TSA assumes the

[11] *See* 49 CFR 1548.7(b).

[12] *See* 49 CFR 1548.7(f) and (g), citing 49 CFR 1540.301.

[13] *See, e.g., supra* n. 10.

[14] *See supra* n. 8 and accompanying text.

aggregate population of active and approved IACs under the baseline and the proposed rule decreases each year with more dropping out than entering. TSA calculates that the aggregate active population decreases at an annual rate of 1.61 percent [15] and compounds this rate to estimate the aggregate active IAC population for the next ten years, as displayed in column *a* of Table 2. The aggregate active population of IACs (column *a*) also represents the number of security program submissions and resubmissions under the baseline annual renewal requirement.

TSA postulates that the number of newly approved IAC applications represents a proportion of the number of aggregate active IACs in the same year. This proportion has stabilized over the last five years at 5.41 percent. TSA applied this percentage to the forecasted aggregate number of active IACs during a year to estimate the number of newly approved IAC applications during the same year [16] as displayed in column *c* of Table 2.

The aggregate active population of IACs during a year is composed of IAC renewals and newly approved IAC applications. Since TSA calculates the number of newly approved IAC applications by assuming they are a constant proportion of the number of aggregate active IACs, then the number of renewals must be estimated applying the complementary proportion to the number of aggregate active IACs, as shown in column *b* of Table 2.[17]

The exit rate of IAC in a given year is based on the subtraction of the given year's active IAC population from the preceding year's active IAC population, and the removal of the given year's newly approved IACs,[18] as displayed in column *d* of Table 2. Since the number of IAC exits is estimated based on the number of active IACs during the year and the number of newly approved IAC applications, an exit rate is derived from these two estimates for the purposes of compounding the number of exits over time. TSA calculates an IAC exit rate of 6.92 percent [19] (*i.e.,* do not resubmit or are not approved) from year to year. The exit rate in a specific year is the percentage of IACs that do not request their security program renewed [20] out of the total number of IACs that had a security program in place prior to this year.

TSA estimates the total number of submissions in two blocks: the first block includes submissions associated with the current IAC population in each year, and the second block includes submissions from new applicants. This proposed rule is expected to be implemented in 2023 (year 1) and the relevant 2022 active IAC population will have, by then, a valid security plan; which will have to be renewed following the new three-year cycle.[21] New applicants would also have to follow this three-year renewal cycle. In both blocks, there is a share of IAC firms that will not renew their security plans during the next renewal event, and a share of IAC firms that will renew. The number of IACs resubmitting in a given year is estimated by multiplying the number of program submissions from three years prior by a factor that results from compounding the annual exit rate over three years; this retention factor, estimated to be 80.6 percent,[22] is multiplied by the number of program submissions from three years prior to estimate the number of renewals in the corresponding year.

Table 2 staggers recertifications under the final rule's three-year cycle [23] in four separate columns for submissions one to four in the 10-year projection span. For example, TSA estimates that 2,738 of the 3,395 IAC recertifications in year 1 would resubmit their security programs in year 4, [24] and that 159 of the 197 new entrants in year 1 would resubmit for the first time in year 4 (see columns *e* and *f* regarding first and second submissions). In Table 2, TSA takes into account four recertification cycles [25] within the ten-year framework (columns *e* through *h*) and sums all the recertifications under the proposed rule in column *i*. Finally, TSA calculates the number of eliminated recertifications (column *j*) by subtracting the proposed rule recertifications (column *i*) from the baseline annual recertifications (column *b*).

[15] Based on TSA data, there were 4,576 IACs in 2008 and 3,768 in 2020. TSA calculates a negative compound annual growth rate of 1.61% = (3,768 ÷ 4,576) (1 ÷ (2020—2008)) − 1.

[16] The number of aggregate active IACs is estimated using the previous year aggregate value and the negative growth rate. For instance, the year 0 (2022) aggregate number of active IACs of 3,648 is estimated applying the negative growth rate to the year −1 (2021) aggregate number of 3,707: 3,648 = 3,707 × (1–1.61%). The number of new IAC applications in year 0 is estimated at 197 by multiplying the estimated number of aggregate IACs in year 0 (3,648) by the average proportion of new IAC applications: 197 = 3,648 × 5.41%.

[17] The number of IAC renewals is estimated applying the percentage complementary to the proportion of new IAC applications (1–5.41%) into the aggregate number of active IACs. For instance, the year 0 (2022) number of renewals is estimated multiplying the number of aggregate active IACs, or 3,648, by the complementary percentage of 94.59% to obtain 3,451 (3,648 × 94.59%). The number of IAC renewals can also be estimated subtracting the number of newly approved IAC applications from the number of aggregate active IACs.

[18] For example, calculations of Year 0, Year 1 and Year 2 IAC Exits are as follows:

− 257 (Year 0 Exits) = 3,648 (Year 0 Active IACs) − 3,707 (Year –1 Active IACs) − 197 (Year 0 Newly Approved IACs);

− 253 (Year 1 Exits) = 3,589 (Year 1 Active IACs) − 3,648 (Year 0 Active IACs) − 194 (Year 1 Newly Approved IACs);

− 249 (Year 2 Exits) = 3,532 (Year 2 Active IACs) − 3,395 (Year 1 Active IACs) − 191 (Year 2 Newly Approved IACs).

[19] The exit rate is estimated by dividing the number of IAC exits by the aggregate number of active IACs in the previous year. For example, TSA estimates there would be 257 exits in year 0 (197 exits that were replaced by new entrants plus the 60 exits that decreased the aggregate population). TSA calculates a 6.92% exit rate in year 0 (257 exits ÷ 3,707 aggregate active IACs in year −1). This exit rate is the same throughout the ten-year period of analysis. The exit rate for future years can also be derived mathematically as follows: (Newly Approved IAC Proportion) × (1 + Active IAC Growth Rate) − (Active IAC Growth Rate), which numerically is equal to: 6.92% = 5.41% (1 − 1.61%) − (− 1.61%).

[20] Firms do not get renewals either because a submission was not filed or was not approved.

[21] It is assumed that the validity of security plans will be extended until year 1 once this action is executed. If an IAC firm in the year 0 population wants to remain active over the 10 years of analysis it will have to obtain four renewals during this period, in years 1, 4, 7, and 10.

[22] 80.6% = (100% − 6.92% exit rate)$^{(3\ year\ cycle)}$.

[23] A cycle is the period in between renewals (or between the first renewal and the initial approval). The three-year cycle means that submissions have to be renewed every three years. The current submission cycle is annual, one submission every year.

[24] Note IACs that were approved by TSA in year −1 (two years prior to the start date of this rule) and partially in year 0 (one year prior to the publication of this proposed rule) would need to resubmit 36 months from their last approval. IACs that were approved prior to the publication of the proposed rule (− 1 & 0) are included in year −1, for the purpose of this analysis. For example: (Year 4 Second Cycle Resubmissions) = (Year 1 Renewals) × 80.6%

[25] The frequency in which an IAC must resubmit their security program for review.

TABLE 2— NUMBER OF PROPOSED RULE ELIMINATED SECURITY PROGRAM RECERTIFICATIONS

Year	Active IACs[26]	Baseline recerts[27]	New IACs	IAC exits	Recertification cycle[28]				Proposed rule recerts	Eliminated recerts
					1st	2nd	3rd	4th		
	a(−1) = initial pop a = a(n−1) × (1−1.61%)	b1 = first year renewals bn = an × (1−5.41%)	c = an × (5.41%)	dn = (an−a(n−1))−cn	e1 = b1 en = c(n−3) × (0.806)	fn = e(n−3) × (0.806)	gn = f(n−3) × (0.806)	hn = g(n−3) × (0.806)	i = e + f + g + h	j = b−i
1	3,589	3,395	194	−253	3,395	0	0	0	3,395	0
2	3,532	3,341	191	−249	162	0	0	0	162	3,179
3	3,475	3,287	188	−245	159	0	0	0	159	3,128
4	3,419	3,234	185	−241	156	2,738	0	0	2,894	340
5	3,364	3,182	182	−237	154	130	0	0	284	2,898
6	3,310	3,131	179	−233	151	128	0	0	280	2,852
7	3,257	3,081	176	−229	149	126	2,207	0	2,483	598
8	3,205	3,032	173	−226	147	124	105	0	376	2,656
9	3,153	2,983	170	−222	144	122	103	0	370	2,613
10	3,103	2,935	168	−218	142	120	102	1,780	2,144	791

Note: Calculations may not be exact due to rounding in the table.

TSA estimates a time burden of four hours for an IAC manager to review and resubmit a security program. To calculate the hourly savings to industry, TSA multiplies the four-hour burden by the fully loaded hourly wage rate for an IAC manager. TSA calculates the wage rate by estimating a weighted wage rate for two occupations across two industry subgroups.[29] To calculate the weighted wage rate, TSA multiplies each labor category wage rate by its respective number of employees, sums the product of these calculations, and then divides the result by the total number of employees across all four wage rates. Table 3 illustrates the weighted average wage calculation.

TABLE 3—CALCULATION OF WEIGHTED AVERAGE INDUSTRY WAGE RATE

Industry NAICS	Occupations	Wage rate	Number of employees
		a	b
Freight Transportation Arrangement (488510)	First-Line Supervisors of Transportation and Material Moving Workers (53–1040).	$28.72	3,460
	Transportation, Storage, and Distribution Managers (11–3071).	46.41	4,920
Management, Scientific, and Technical Consulting Services (541611).	First-Line Supervisors of Transportation and Material Moving Workers (53–1040).	27.52	3,190
	Transportation, Storage, and Distribution Managers (11–3071).	50.65	2,680
Industry Weighted Average Wage Rate = $\Sigma(a \times b) \div \Sigma b$			$38.68

Note: Calculations may not be exact due to rounding in the table.

Next, TSA adjusts this wage rate to account for employer benefits,[30] which results in an industry compensation rate of $57.90 per hour. Table 4 illustrates the calculation of the hourly industry compensation rate based on these adjustments.

[26] The active IAC population in subsequent years was estimated by applying the negative growth rate of 1.61% to the active IAC population. The negative growth rate represents the net change in the active IAC population accounting for IAC exits and entries. Year 1's value accounts for three years of negative growth derived from 3,768 IACs as of the end of fiscal year 2020 based on TSA records.

[27] Baseline renewals represent Active IACs minus New IACs.

[28] A retention factor of 0.806 is calculated as the exit rate of 6.92 percent compounded over three years to account for the number of IACs still operating who submitted a security program three years prior.

[29] Bureau of Labor Statistics (BLS), U.S. Department of Labor, May 2020 National Industry Specific Occupation Employment and Wage Estimates, First-Line Supervisors of Transportation and Material Moving Workers (SOC 53–1040) in Freight Transportation Arrangement (NAICS 488510) and Administrative Management and General Management Consulting Services (NAICS 541611), and to Transportation, Storage, and Distribution Managers (SOC 11–3071) in (NAICS 488510) and (NAICS 541611). (Accessed May 19, 2021 at *https://www.bls.gov/oes/2020/may/naics4_541600.htm* and *https://www.bls.gov/oes/2020/may/naics4_488500.htm*).

[30] The average compensation factor is 1.4968. 1.4968 = (($31.76 + $30.89 + $30.99 + $30.40) ÷ 4) ÷ (($21.35 + $20.62 + $20.61 + $20.29) ÷ 4). The compensation factor is calculated based on the average of the quarterly total compensation divided by the average of the quarterly total wages. Source: BLS, News Releases, *2020 Employer Costs for Employee Compensation,* Table 4: Employer Costs for Employee Compensation for private industry workers by occupational and industry group (Transportation and Material Moving Occupational Group), as published in June 2020, September 2020, December 2020, and March 2021. (Accessed May 19, 2021 at *https://www.bls.gov/bls/news-release/ecec.htm).*

TABLE 4—CALCULATION OF INDUSTRY COMPENSATION RATE

Weighted wage rate (a)	Benefits Factor (b)	Compensation Rate (c = a × b)
$38.68	1.4968	$57.90

TSA multiplies four hours per resubmission by the $57.90 for an IAC manager to calculate a unit cost savings of $232 per recertification.[31]

TSA estimates a duration of 2.25 hours for TSA staff to review a resubmission. The TSA review staff is composed of two ''I'' pay band members [32] and four ''J'' pay band members. Each submission could be reviewed by any one of these staff members. TSA calculates a staff compensation rate based on the weighted average of two different TSA pay-bands that conduct reviews. To calculate the TSA weighted compensation rate, TSA multiplies the respective pay band compensation [33] by the respective number of employees, sums the product of these calculations, and then divides by the total number of employees. Table 5 displays this weighted average calculation.

TABLE 5—CALCULATION OF WEIGHTED AVERAGE TSA COMPENSATION RATE

TSA pay band	Compensation rate *	Number of employees
	a	b
TSA I Band	$70.62	2
TSA J Band	83.17	4
Weighted Average TSA Compensation Rate = $\Sigma(a \times b) \div \Sigma b$	$78.99	

* Compensation Rate includes employer benefits.

TSA multiplies 2.25 hours by the TSA compensation rate of $78.99 per hour to obtain a unit cost savings per recertification of $178.[34]

To calculate savings, TSA multiplies the number of eliminated resubmissions from column j of Table 2, by the respective unit cost savings for industry ($232) and TSA ($178). Table 6 displays the industry, TSA, and total savings from modifying the security program resubmission frequency from one to three years. TSA estimates that over ten years cost savings aggregate to $7.8 million undiscounted, $6.6 million discounted at 3 percent, and $5.4 million discounted at 7 percent. The proposed rule would realize an annualized $0.8 million cost savings discounted at 7 percent over 10 years.

TABLE 6—TOTAL COST SAVINGS FROM THE PROPOSED RULE

[$Thousands]

Year	Eliminated resubmissions	Industry savings	TSA savings	(Cost savings) d = Σb,c		
	a	b = a × $231.61 ÷ 1,000	c = a × $177.73 ÷ 1,000	Undiscounted	Discounted at 3%	Discounted at 7%
1		$0	$0	$0	$0	$0
2	3,179	736	565	1,301	1,227	1,137
3	3,128	725	556	1,280	1,172	1,045
4	340	79	60	139	124	106
5	2,898	671	515	1,186	1,023	846
6	2,852	660	507	1,167	978	778
7	598	139	106	245	199	153
8	2,656	615	472	1,087	858	633
9	2,613	605	464	1,070	820	582
10	791	183	141	324	241	165
Total	19,056	4,413	3,387	7,800	6,641	5,443
Annualized					775	779

Note: Calculation may not be exact in table due to rounding.

[31] $231.61 Renewal Unit Cost to Industry = 4-Hour Renewal Time Burden × $57.90 Compensation Rate for IAC Managers.

[32] TSA uses an SV pay grading system, which is a discrete salary system with pay ranges, incorporated into pay bands.

[33] TSA, DHS Modular Cost Standards, Washington DC Metropolitan Area Locality Pay, I-Band $70.62 = $147,382 annual compensation ÷ 2,087 hours and J-Band $83.17 = $173,585 annual compensation ÷ 2,087 hours (Office Personnel Management changed the 2,080 work hours for Federal employees to 2,087 by amending 5 U.S.C. 5504(b). Source: Consolidated Omnibus Budget Reconciliation Act of 1985, Public Law 99–272, 100 Stat. 82 (April 7, 1986).

[34] $177.73 Renewal Unit Cost to TSA = $78.99 I/J Band TSA Weighted Compensation Rate × 2.25 Hour Burden for Renewal Review.

The Regulatory Flexibility Act [35] requires agencies to consider whether some rules would have a significant economic impact on a substantial number of small entities, including small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. This rule does not place any new requirements on the regulated industry or small businesses.

C. Collection of Information

The Paperwork Reduction Act of 1995 (PRA) [36] requires Federal agencies to consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from the OMB for each collection of information it conducts, sponsors, or requires through regulations. As provided by the PRA, as amended, 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 collection of information covered by this proposed rule is covered by OMB control number 1652–0040.

This proposed rule impacts the collection of information by reducing the frequency that information must be submitted. This reduction would decrease the current number of security program recertifications submitted from an estimated annual average of 3,700 to 1,239 responses (a reduction of 2,461). The corresponding burden is also reduced from an annual average of 14,800 hours to 4,956 hours (a reduction of 9,844 hours). Table 7 displays the annual number of responses and burden hour estimates associated with the proposed rule.

TABLE 7—PRA INFORMATION COLLECTION RESPONSES AND BURDEN HOURS

Collection activity	Responses						Total hours	Average annual hours
	Year 1	Year 2	Year 3	Total responses	Average annual responses	Time burden per response (hours)		
Proposed Rule Recerts	3,395	162	159	3,716	1,239		4,956	1,652

As required by the PRA (44 U.S.C. 3507(d)), TSA has submitted a copy of the proposed rule to the OMB for its review of the collection of information.

D. International Trade Impact Assessment

The Trade Agreements Act of 1979 [37] prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these requirements, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

TSA has assessed the potential effect of the proposed rule and determined that it does not impose any new requirements. Therefore, the rule will not create any unnecessary obstacles to foreign commerce of the United States.

E. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 [38] requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed agency rule, or final rule for which a proposed rule was published, that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector. The proposed rule does not contain such a mandate. Therefore, the written statement requirements of the Act do not apply.

F. Environment

TSA reviews proposed actions to determine whether the National Environmental Policy Act (NEPA) applies to them, and if so, what degree of analysis is required. DHS Directive 023–01 Rev. 01 and Instruction Manual 023–01–001–01 Rev. 01 establish the procedures that DHS and its components use to comply with NEPA and the Council on Environmental Quality (CEQ) regulations for implementing NEPA, 40 CFR parts 1500 through 1508.

The CEQ regulations allow Federal agencies to establish, with CEQ review and concurrence, categories of actions (categorical exclusions) which experience has shown do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment or Environmental Impact Statement.[39] For an action to be categorically excluded, it must satisfy each of the following three conditions: (1) the entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect.[40]

This rulemaking has no anticipated environmental effects. Specifically, this proposed rule extends the duration of TSA approval of IAC security programs for up to three years without modifying standards or imposing an additional burden on regulated entities. It fits within categorical exclusion A3(d), ''Promulgation of rules . . . that interpret or amend an existing regulation without changing its environmental effect.'' [41] Furthermore, the proposed rule is not part of a larger action and presents no extraordinary circumstances creating the potential for significant environmental impacts. As such, the amendment is categorically excluded from further NEPA review.

[35] *See* Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) as codified at 5 U.S.C. 601 *et seq.*

[36] *See* 44 U.S.C. 3501 *et seq.*

[37] *See* Public Law 96–39, 93 Stat. 144 (July 26, 1979) as amended by the Uruguay Round Agreements Act, Public Law 103–465, 108 Stat 4809 (Dec. 8, 1994), codified at 19 U.S.C. 2531–2533.

[38] *See* Public Law 104–4, 109 Stat. 48 (Mar. 22, 1995), codified at 2 U.S.C. 1501–1538.

[39] 40 CFR 1507.3(b)(2)(ii), 1508.4.

[40] *See* Instruction Manual, section V.B(2)(a)–(c).

[41] *See id.* at Appendix A, Table 1.

G. International Compatibility and Cooperation

E.O. 13609 of May 1, 2012 (*Promoting International Regulatory Cooperation*),[42] promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. TSA analyzed this action under the policies and agency responsibilities of E.O. 13609, and has determined that this action would have no effect on international regulatory cooperation. In keeping with U.S. obligations under the Convention on International Civil Aviation (also known as the ''Chicago Convention''), it is TSA policy to comply with International Civil Aviation Organization Standards and Recommended Practices to the maximum extent practicable. TSA has determined that this regulation has no direct relationship to the Chicago Convention.

H. Executive Order 13132, Federalism

TSA has analyzed this rulemaking under the principles and criteria of E.O. 13132 of August 4, 1999 (*Federalism*).[43] TSA has determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications.

I. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

TSA analyzed this rulemaking under E.O. 13211 of May 18, 2001 (*Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use*).[44] TSA has determined that it is not a ''significant energy action'' under the Executive order and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

List of Subjects in 49 CFR Part 1548

Air transportation, Reporting and recordkeeping requirements, Security measures.

The Amendment

For the reasons set forth in the preamble, the Transportation Security Administration proposes to amend chapter XII of title 49, Code of Federal Regulations, as follows:

SUBCHAPTER C—CIVIL AVIATION SECURITY

PART 1548—INDIRECT AIR CARRIER SECURITY

■ 1. The authority citation for part 1548 continues to read as follows:

Authority: 49 U.S.C. 114, 5103, 40113, 44901–44905, 44913–44914, 44916–44917, 44932, 44935–44936, 46105.

§ 1548.7 [Amended]

■ 2. Amend § 1548.7 by:

■ a. In paragraph (a)(4), removing the words ''one year after the month it was approved'' and adding in their place ''three years after the month it was approved, or until the program has been surrendered or withdrawn, whichever is earlier''.

■ b. In paragraph (a)(5) introductory text, adding the words ''or renewal'' after the words ''submitted during its initial''.

■ c. In paragraph (b)(1), removing the words ''at least 30 calendar days prior to the first day of the anniversary month of initial approval'' and adding in their place ''at least 30 calendar days prior to the 36th month after the initial approval''.

■ d. In paragraph (b)(4), removing the words ''one year after the month it was renewed'' and adding in their place ''three years after the month it was renewed, or until the program has been surrendered or withdrawn, whichever is earlier''.

Dated: December 16, 2022.

David P. Pekoske,

Administrator.

[FR Doc. 2022–27778 Filed 12–23–22; 8:45 am]

BILLING CODE 9110–05–P

[42] Published at 77 FR 26413 (May 4, 2012).

[43] Published at 64 FR 43255 (Aug. 10, 1999).

[44] Published at 66 FR 28355 (May 22, 2001).

Notices

Federal Register
Vol. 87, No. 247
Tuesday, December 27, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0030]

State University of New York College of Environmental Science and Forestry; Availability of a Draft Environmental Impact Statement and Draft Plant Pest Risk Assessment for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (Castanea dentata) Developed Using Genetic Engineering

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability; extension of comment period.

SUMMARY: We are advising the public that we are extending the comment period on a notice of availability of a draft environmental impact statement and draft plant pest risk assessment evaluating the potential environmental impacts and plant pest risk that may result from the approval of a petition for nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*) from the State University of New York College of Environmental Science and Forestry. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the notice published on November 10, 2022 (87 FR 67861–67862) is extended. We will consider all comments that we receive on or before January 26, 2023.

ADDRESSES: You may submit comments by either of the following methods:

- FederaleRulemakingPortal:Go to *www.regulations.gov.* Enter APHIS–2020–0030 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0030, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

The petition and any comments we receive on this docket may be viewed at *Regulations.gov* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 7997039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Subray Hegde, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1238; (301) 851–3901; email: *subray.hegde@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

On November 10, 2022, we published in the **Federal Register** (87 FR 67861–67862), Docket No. APHIS–2020–0030) a notice of availability of a draft environmental impact statement and draft plant pest risk assessment [1] evaluating the potential environmental impacts and plant pest risk that may result from the approval of a petition for nonregulated status for blight-tolerant Darling 58 American chestnut (*Castanea dentata*) from the State University of New York College of Environmental Science and Forestry.

Comments on the notice were required to be received on or before December 27, 2022. We are extending the comment period on Docket No. APHIS–2020–0030 for an additional 30 days. This action will allow interested persons additional time to prepare and submit comments.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 20th day of December 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2022–28075 Filed 12–23–22; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the notice, supporting documents, and public comments, go to *www.regulations.gov.* Enter APHIS–2020–0030 in the Search field.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Farm Service Agency

[Docket ID FSA–2022–0017]

Information Collection Request; Application for Payment of Amounts Due Persons Who Have Died, Disappeared, or Have Been Declared Incompetent

AGENCY: Commodity Credit Corporation and Farm Service Agency, USDA.

ACTION: Notice; correction.

SUMMARY: The Commodity Credit Corporation (CCC) and the Farm Service Agency (FSA) are making a correction to the notice that was published on December 6, 2022. We are making a minor correction specifically in the description of the information collection request section to correct a typographical error in a number.

DATES: We will consider comments that we receive by February 6, 2023.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://regulations.gov.* Go to *http://www.regulations.gov* and search for Docket ID FSA–2022–0017. Follow the online instructions for submitting comments.
- *Mail:* Joe Lewis Jr., Agricultural Program Specialist, USDA, FSA STOP 0572, 1400 Independence Avenue SW, Washington, DC 20250–0572. In your comments, include date, volume, and page number of this issue of the **Federal Register**.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Joe Lewis Jr. at the above address.

FOR FURTHER INFORMATION CONTACT: Mary Ann Ball, by email: *maryann.ball@usda.gov;* by telephone: (202) 720–4283.

SUPPLEMENTARY INFORMATION: We published the notice in the **Federal Register** on December 6, 2022, (87 FR 74595) to request public comments on the Application for Payment of

Amounts Due Persons Who Have Died, Disappeared, or Have Been Declared Incompetent information collection request. This notice is making a minor correction in the Description of Information Collection section. The OMB control number was listed as ''0560–0226'' in the section; the OMB control number should have been listed as ''0560–0026'' for the information collection request covering Application for Payment of Amounts Due Persons Who Have Died, Disappeared, or Have Been Declared Incompetent. This corrects the typographical error in the OMB control number.

Zach Ducheneaux,

Administrator, Farm Service Agency, and Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2022–28106 Filed 12–23–22; 8:45 am]

BILLING CODE 3411–EZ–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Notice of a Request for Extension of a Currently Approved Information Collection

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act, this notice announces the Foreign Agricultural Service's intention to request an extension of 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 February 27, 2023 to be assured of consideration.

ADDRESSES: You may send comments, identified by Office of Management and Budget (OMB) Control Number 0551–0014, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* This portal enables respondents to enter short comments or attach a file containing lengthier comments.
- *Email: William.Janis@usda.gov.* Include OMB Control number 0551–0014 in the subject line of the message.
- Mail, hand delivery, or courier: William Janis, Multilateral Affairs Division, Trade Policy and Geographic Affairs, Foreign Agricultural Service, U.S. Department of Agriculture, Room 5550, Stop 1070, 1400 Independence Ave. SW, Washington, DC 20250–1070.

Instructions: All submissions received must include the agency names and OMB Control Number for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: *William.Janis@usda.gov,* 202–720–2194, *William.Janis@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certificates of Quota Eligibility.

OMB Number: 0551–0014.

Expiration Date of Approval: June 30, 2023.

Type of Request: Extension 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—Certificate of Quota Eligibility, 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 free trade agreement (FTA) sugar TRQs are distributed to foreign countries by the Senior Director of the Multilateral Affairs Division, Foreign Agriculture Service, or 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.

Type of Respondents: Foreign governments.

Estimated Number of WTO Respondents: 30.

Estimated Number of FTA Respondents: 2.

Estimated Number of Responses per Respondent: 124.

Estimated Total Annual Reporting Burden: 3,968 hours.

Copies of this information collection can be obtained from Dacia Rogers, the Agency Information Collection Coordinator, at *Dacia.Rogers@usda.gov.*

Request for Comments: Send comments regarding (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden 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.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be available without change, including any personal information provided, for inspection online at *http://www.regulations.gov* and at the mail address listed above between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Comments will be summarized and included in the submission for OMB approval.

Persons with disabilities who require an alternative means for communication of information (Braille, large print,

audiotape, etc.) should contact *FAS-ReasonableAccommodation@usda.gov* or Felice Robinson (Senior Reasonable Accommodations Specialist), *Felice.Robinson@usda.gov.*

Daniel Whitley,

Administrator, Foreign Agricultural Service.

[FR Doc. 2022–28117 Filed 12–23–22; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–38–2022]

Foreign-Trade Zone (FTZ) 45—Portland, Oregon, Authorization of Production Activity, Epson Portland Inc. (Inkjet Ink Printer Bottles (Empty and Filled) For Retail Sale), Hillsboro, Oregon

On August 23, 2022, Epson Portland Inc., submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 45F, in Hillsboro, Oregon.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (87 FR 53456–53457, August 31, 2022). On December 21, 2022, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: December 21, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–28135 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Washington, DC 20230; Nordwind Airlines, Leningradskaya str., Building 25, office 27. 28, Moscow Region, Khimki city, 141402, Russia

Order Renewing Temporary Denial of Export Privileges

Pursuant to Section 766.24 of the Export Administration Regulations, 15 CFR parts 730–774 (2021) (''EAR'' or ''the Regulations''),[1] I hereby grant the request of the Office of Export Enforcement (''OEE'') to renew the temporary denial order (''TDO'') issued in this matter on June 24, 2022. I find that renewal of this order is necessary in the public interest to prevent an imminent violation of the Regulations.

I. Procedural History

On June 24, 2022, I signed an order denying the export privileges of Nordwind Airlines (''Nordwind'') for a period of 180 days on the ground that issuance of the order was necessary in the public interest to prevent an imminent violation of the Regulations. The order was issued *ex parte* pursuant to Section 766.24(a) of the Regulations and was effective upon issuance.[2]

On December 1, 2022, BIS, through OEE, submitted a written request for renewal of the TDO that issued on June 24, 2022. The written request was made more than 20 days before the TDO's scheduled expiration. A copy of the renewal request was sent to Nordwind in accordance with Sections 766.5 and 766.24(d) of the Regulations. No opposition to the renewal of the TDO has been received.

II. Renewal of the TDO

A. Legal Standard

Pursuant to Section 766.24, BIS may issue an order temporarily denying a respondent's export privileges upon a showing that the order is necessary in the public interest to prevent an ''imminent violation'' of the Regulations, or any order, license or authorization issued thereunder. 15 CFR 766.24(b)(1) and 766.24(d). ''A violation may be 'imminent' either in time or degree of likelihood.'' 15 CFR 766.24(b)(3). BIS may show ''either that a violation is about to occur, or that the general circumstances of the matter under investigation or case under criminal or administrative charges demonstrate a likelihood of future violations.'' *Id.* As to the likelihood of future violations, BIS may show that the violation under investigation or charge ''is significant, deliberate, covert and/or likely to occur again, rather than technical or negligent[.]'' *Id.* A ''lack of information establishing the precise time a violation may occur does not preclude a finding that a violation is imminent, so long as there is sufficient reason to believe the likelihood of a violation.'' *Id.*

B. The TDO and BIS's Request for Renewal

The U.S. Commerce Department, through BIS, responded to the Russian Federation's (''Russia's'') further invasion of Ukraine by implementing a sweeping series of stringent export controls that severely restrict Russia's access to technologies and other items that it needs to sustain its aggressive military capabilities. These controls primarily target Russia's defense, aerospace, and maritime sectors and are intended to cut off Russia's access to vital technological inputs, atrophy key sectors of its industrial base, and undercut Russia's strategic ambitions to exert influence on the world stage. Effective February 24, 2022, BIS imposed expansive controls on aviation-related (*e.g.,* Commerce Control List Categories 7 and 9) items to Russia, including a license requirement for the export, reexport or transfer (in-country) to Russia of any aircraft or aircraft parts specified in Export Control Classification Number (ECCN) 9A991 (Section 746.8(a)(1) of the EAR).[3] BIS will review any export or reexport license applications for such items under a policy of denial. *See* Section 746.8(b). Effective March 2, 2022, BIS excluded any aircraft registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia from being eligible for license exception Aircraft, Vessels, and Spacecraft (AVS) (Section 740.15 of the EAR).[4] Accordingly, any U.S.-origin aircraft or foreign aircraft that includes more than 25% controlled U.S.-origin content, and that is registered in, owned, or controlled by, or under charter or lease by Russia or a national of Russia, is subject to a license

[1] On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, 50 U.S.C. 4801–4852 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the Export Administration Act, 50 U.S.C. App. § 2401 *et seq.* (''EAA''), (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all orders, rules, regulations, and other forms of administrative action that were made or issued under the EAA, including as continued in effect pursuant to the International Emergency Economic Powers Act, 50 U.S.C. 1701 *et seq.* (''IEEPA''), and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA. Moreover, Section 1761(a)(5) of ECRA authorizes the issuance of temporary denial orders. 50 U.S.C. 4820(a)(5).

[2] The TDO was published in the **Federal Register** on June 29, 2022 (87 FR 38704).

[3] 87 FR 12226 (Mar. 3, 2022). Additionally, BIS published a final rule effective April 8, 2022, which imposed licensing requirements on items controlled on the Commerce Control List (''CCL'') under Categories 0–2 that are destined for Russia or Belarus. Accordingly, now all CCL items require export, reexport, and transfer (in-country) licenses if destined for or within Russia or Belarus. 87 FR 22130 (Apr. 14, 2022).

[4] 87 FR 13048 (Mar. 8, 2022).

requirement before it can travel to Russia.

OEE's request for renewal is based upon the facts underlying the issuance of the initial TDO and the evidence developed over the course of this investigation, which indicate a blatant disregard for U.S. export controls, as well as the TDO. Specifically, the initial TDO, issued on June 24, 2022, was based on evidence that Nordwind engaged in conduct prohibited by the Regulations by operating multiple aircraft subject to the EAR and classified under ECCN 9A991.b on flights into Russia after March 2, 2022 from destinations including, but not limited to, Yerevan, Armenia, Istanbul, Turkey, and Sharm el-Sheikh, Egypt, without the required BIS authorization.[5]

In its December 1, 2022, request for renewal of the TDO, BIS has submitted evidence that Nordwind continues to operate in violation of the June 24, 2022 TDO and/or the Regulations by operating aircraft subject to the EAR and classified under ECCN 9A991.b. Specifically, BIS's evidence and related investigation indicates that after the issuance of the TDO, Nordwind continued to fly aircraft into Russia in violation of the EAR, including flights from Hurghada, Egypt, Sharm el-Sheikh, Egypt, and Bokhtar, Tajikistan. Information about those flights includes, but is not limited to, the following:

Tail No.	Serial No.	Aircraft type	Departure/arrival cities	Dates
RA–73313	35700	737–82R (B738)	Bokhtar, TJ/Moscow, RU	November 29, 2022.
RA–73313	35700	737–82R (B738)	Hurghada, EG/Kazan, RU	December 2, 2022.
RA–73313	35700	737–82R (B738)	Hurghada, EG/Perm, RU	December 3, 2022.
RA–73313	35700	737–82R (B738)	Hurghada, EG/Kazan, RU	December 5, 2022.
RA–73313	35700	737–82R (B738)	Hurghada, EG/Yekaterinburg, RU	December 8, 2022.
RA–73317	40874	737–82R (B738)	Hurghada, EG/Kazan, RU	November 26, 2022.
RA–73317	40874	737–82R (B738)	Hurghada, EG/Yekaterinburg, RU	November 30, 2022.
RA–73317	40874	737–82R (B738)	Hurghada, EG/Chelyabinsk, RU	December 1, 2022.
RA–73317	40874	737–82R (B738)	Hurghada, EG/Moscow, RU	December 2, 2022.
RA–73319	42059	737–8SH (B738)	Hurghada, EG/Moscow, RU	November 30, 2022.
RA–73319	42059	737–8SH (B738)	Bokhtar, TJ/Moscow, RU	December 1, 2022.
RA–73319	42059	737–8SH (B738)	Bokhtar, TJ/Moscow, RU	December 2, 2022.
RA–73319	42059	737–8SH (B738)	Sharm el-Sheikh, EG/Orenberg, RU	December 3, 2022.
RA–73319	42059	737–8SH (B738)	Hurghada, EG/Moscow, RU	December 6, 2022.

III. Findings

Under the applicable standard set forth in Section 766.24 of the Regulations and my review of the entire record, I find that the evidence presented by BIS convincingly demonstrates that Nordwind has acted in violation of the Regulations and the TDO; that such violations have been significant, deliberate and covert; and that given the foregoing and the nature of the matters under investigation, there is a likelihood of imminent violations. Therefore, renewal of the TDO is necessary in the public interest to prevent imminent violation of the Regulations and to give notice to companies and individuals in the United States and abroad that they should avoid dealing with Nordwind, in connection with export and reexport transactions involving items subject to the Regulations and in connection with any other activity subject to the Regulations.

IV. Order

It is therefore ordered:

First Nordwind Airlines, Leningradskaya str., building 25, office 27. 28, Moscow region, Khimki city, 141402, Russia, when acting for or on their behalf, any successors or assigns, agents, or employees may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the EAR, or in any other activity subject to the EAR including, but not limited to:

A. Applying for, obtaining, or using any license (except directly related to safety of flight), license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations, or engaging in any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the EAR, or from any other activity subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations.

Second, that no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of Nordwind any item subject to the EAR except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by Nordwind of the ownership, possession, or control of any item subject to the EAR that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby Nordwind acquires or attempts to acquire such ownership, possession or control except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from Nordwind of any item subject to the EAR that has been exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations;

D. Obtain from Nordwind in the United States any item subject to the EAR with knowledge or reason to know that the item will be, or is intended to be, exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations; or

[5] Publicly available flight tracking information shows, for example, that on March 7, 2022, serial number (''SN'') 40874 flew from Yerevan, Armenia to Kazan, Russia; SN 40233 flew from Istanbul, Turkey to Kazan, Russia; and SN 40236 flew from Sharm el-Sheikh, Egypt to Moscow, Russia.

E. Engage in any transaction to service any item subject to the EAR that has been or will be exported from the United States and which is owned, possessed or controlled by Nordwind, or service any item, of whatever origin, that is owned, possessed or controlled by Nordwind if such service involves the use of any item subject to the EAR that has been or will be exported from the United States except directly related to safety of flight and authorized by BIS pursuant to Section 764.3(a)(2) of the Regulations. For purposes of this paragraph, servicing means installation, maintenance, repair, modification, or testing.

Third, that, after notice and opportunity for comment as provided in section 766.23 of the EAR, any other person, firm, corporation, or business organization related to Nordwind by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order.

In accordance with the provisions of Sections 766.24(e) of the EAR, Nordwind may, at any time, appeal this Order by filing a full written statement in support of the appeal with the Office of the Administrative Law Judge, U.S. Coast Guard ALJ Docketing Center, 40 South Gay Street, Baltimore, Maryland 21202–4022.

In accordance with the provisions of Section 766.24(d) of the EAR, BIS may seek renewal of this Order by filing a written request not later than 20 days before the expiration date. A renewal request may be opposed by Nordwind as provided in Section 766.24(d), by filing a written submission with the Assistant Secretary of Commerce for Export Enforcement, which must be received not later than seven days before the expiration date of the Order.

A copy of this Order shall be provided to Nordwind and shall be published in the **Federal Register**.

This Order is effective immediately and shall remain in effect for 180 days.

Matthew S. Axelrod,

Assistant Secretary of Commerce for Export Enforcement.

[FR Doc. 2022–28029 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–523–813]

Polyethylene Terephthalate Sheet From the Sultanate of Oman: Preliminary Results of Changed Circumstances Review and Intent To Revoke the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On November 18, 2022, the U.S. Department of Commerce (Commerce) initiated a changed circumstances review (CCR) of the antidumping duty order on polyethylene terephthalate (PET) sheet from the Sultanate of Oman (Oman). We preliminarily determine that revocation of the order is warranted. Interested parties are invited to comment on these preliminary results.

DATES: Applicable December 27, 2022.

FOR FURTHER INFORMATION CONTACT: Brittany Bauer, 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) 482–3860.

SUPPLEMENTARY INFORMATION:

Background

On September 10, 2020, Commerce published the antidumping duty order on PET sheet from Oman.[1] On October 26, 2022, the petitioners [2] (*i.e.,* domestic producers of subject merchandise) requested, through a CCR, revocation of the *Order,* pursuant to section 751(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.222(g)(1).[3] Commerce published the notice of initiation of the CCR on November 18, 2022.[4] Because the petitioners did not indicate whether they account for substantially all of the domestic production of PET sheet, in the *Initiation Notice* we invited interested parties to submit comments regarding industry support for the potential revocation, as well as comments and/or factual information regarding the CCR.

On November 22, 2022, OCTAL Extrusion Corporation (OCTAL Extrusion), a U.S. producer of PET sheet, submitted comments in support of the revocation of the *Order*.[5] We received no further comments on the *Initiation Notice*.

Scope of the Order

The merchandise covered by the *Order* is raw, pretreated, or primed polyethylene terephthalate sheet, whether extruded or coextruded, in nominal thicknesses of equal to or greater than 7 mil (0.007 inches or 177.8 μm) and not exceeding 45 mil (0.045 inches or 1143 μm) (PET sheet). The scope includes all PET sheet whether made from prime (virgin) inputs or recycled inputs, as well as any blends thereof. The scope includes all PET sheet meeting the above specifications regardless of width, color, surface treatment, coating, lamination, or other surface finish.

The merchandise subject to the *Order* is properly classified under statistical reporting subheading 3920.62.0090 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope is dispositive.

Preliminary Results of the Changed Circumstances Review and Intent To Revoke the Order

Pursuant to section 751(d)(1) of the Act, and 19 CFR 351.222(g), Commerce may revoke an antidumping or countervailing duty order, in whole or in part, based on a review under section 751(b) of the Act (*i.e.,* a CCR). Section 751(b)(1) of the Act requires a CCR to be conducted upon receipt of a request which shows changed circumstances sufficient to warrant a review. Section 782(h)(2) of the Act gives Commerce the authority to revoke an order if producers accounting for substantially all of the production of the domestic like product have expressed a lack of interest in the order. Section 351.222(g) of Commerce's regulations provides that Commerce will conduct a CCR under 19 CFR 351.216, and may revoke an order (in whole or in part), if it concludes that: (i) producers accounting for substantially all of the production of the domestic like product to which the order pertains have expressed a lack of interest in the relief provided by the order, in whole or

[1] *See Polyethylene Terephthalate Sheet from the Republic of Korea and the Sultanate of Oman: Antidumping Duty Orders,* 85 FR 55824 (September 10, 2020) (*Order*).

[2] The petitioners are Advanced Extrusion, Inc., Good Natured Products, IL dba Ex-Tech Inc., and Multi-Plastics Extrusions, Inc.

[3] *See* Petitioners' Letter, ''Request for a 'No Interest' Changed Circumstances Review and Revocation of the Order,'' dated October 26, 2022.

[4] *See Polyethylene Terephthalate Sheet from the Sultanate of Oman: Notice of Initiation of Changed Circumstances Review and Consideration of Revocation of the Antidumping Duty Order,* 87 FR 69252 (November 18, 2022) (*Initiation Notice*).

[5] *See* OCTAL Extrusion's Letter, ''OCTAL Extrusion's Comments Supporting Revocation of AD Order,'' dated November 22, 2022 (OCTAL Extrusion's Letter).

in part; or (ii) if other changed circumstances sufficient to warrant revocation exist. Both the Act and Commerce's regulations require that ''substantially all'' domestic producers express a lack of interest in the order for Commerce to revoke the order, in whole or in part.[6] In its administrative practice, Commerce has interpreted ''substantially all'' to represent producers accounting for at least 85 percent of U.S. production of the domestic like product.[7]

Commerce did not issue a combined notice of initiation and preliminary results in this CCR because the record was unclear as to whether the petitioners account for substantially all domestic production of PET sheet.[8] Thus, Commerce did not determine in the *Initiation Notice* whether producers accounting for substantially all of the production of the domestic like product lacked interest in maintaining the *Order*. Instead, we invited interested parties to submit comments concerning domestic industry support with respect to the requested revocation of the *Order*.[9] Although OCTAL Extrusion submitted comments in response to the initiation of this CCR, it did not comment on whether it, or the petitioners, account for substantially all domestic production of PET sheet.[10] Commerce, therefore, received no additional comments on industry support aside from comments by a domestic producer of PET sheet, OCTAL Extrusion, in support of the revocation. As a result, we find that the domestic industry has expressed no opposition with respect to the proposed revocation of the *Order*.

In light of the petitioners' statement of lack of interest, OCTAL Extrusion's comments in support of the revocation, and the absence of comments from any interested party addressing the issue of domestic industry support, we preliminarily conclude that producers accounting for substantially all of the production of the domestic like product to which the *Order* pertains lack interest in the relief provided by the *Order*. Thus, we preliminarily determine that changed circumstances warrant revocation of the *Order*. We will consider comments from interested parties on these preliminary results before issuing the final results of this review.

Accordingly, we are notifying the public of our intent to revoke the *Order*. If we make a final determination to revoke the *Order,* then section 751(d)(3) of the Act provides that ''{a} determination under this section to revoke an order . . . shall apply with respect to unliquidated entries of the subject merchandise which are entered, or withdrawn from warehouse, for consumption on or after the date determined by the administering authority.'' Consequently, Commerce's general practice is to instruct U.S. Customs and Border Protection (CBP) to liquidate without regard to antidumping and countervailing duties, and to refund any estimated deposits of those duties, on all unliquidated entries of the merchandise covered by a revocation that are not covered by the final results of an administrative review or automatic liquidation.[11] However, certain unliquidated entries are currently enjoined from liquidation by litigation. Thus, Commerce is also requesting comments from interested parties regarding the treatment of entries that are covered by this revocation request but remain enjoined due to an injunction issued in ongoing litigation.

Public Comment

Interested parties are invited to comment on these preliminary results, as well as the treatment of unliquidated entries covered by an injunction, in accordance with 19 CFR 351.309(c)(1)(ii). Written comments may be submitted to Commerce no later than 14 days after the date of publication of these preliminary results. Rebuttal comments, limited to issues raised in such comments, may be filed with Commerce no later than seven days after the initial comments are filed.[12] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[13] All submissions must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. An electronically-filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the due date set forth in this notice.

Final Results of the Changed Circumstances Review

Commerce's regulations provide that it will issue the final results of a CCR, which will include analysis of any written comments, no later than 270 days after the date on which a review was initiated, or within 45 days if all parties to the proceeding agree to the outcome of the review.[14] If, in the final result of this review, Commerce continues to determine that changed circumstances warrant the revocation of the *Order,* we intend to instruct CBP to liquidate without regard to antidumping duties, and to refund any deposits of estimated antidumping duties, on all unliquidated entries of the merchandise covered by the revocation that are not covered by the final results of an administrative review or automatic liquidation.[15] The current requirement for cash deposit of estimated antidumping duties on all entries of subject merchandise will continue unless they are modified pursuant to the final results of this CCR.

Notification to Interested Parties

These preliminary results of review are being issued and published in accordance with sections 751(b) and 777(i) of the Act, and 19 CFR 351.216, 19 CFR 351.221(c)(3), and 19 CFR 351.222.

[6] *See* section 782(h) of the Act and 19 CFR 351.222(g).

[7] *See Honey from Argentina; Antidumping and Countervailing Duty Changed Circumstances Reviews; Preliminary Intent to Revoke Antidumping and Countervailing Duty Orders,* 77 FR 67790, 67791 (November 14, 2012), unchanged in *Honey from Argentina; Final Results of Antidumping and Countervailing Duty Changed Circumstances Reviews; Revocation of Antidumping and Countervailing Duty Orders,* 77 FR 77029 (December 31, 2012).

[8] *See Initiation Notice*.

[9] *Id.,* 87 FR at 69253.

[10] *See* OCTAL Extrusion's Letter.

[11] *See, e.g., Certain Pasta from Italy: Final Results of Countervailing Duty Changed Circumstances Review and Revocation, In Part,* 76 FR 27634 (May 12, 2011); *Stainless Steel Bar from the United Kingdom: Notice of Final Results of Changed Circumstances Review and Revocation of Order, in Part,* 72 FR 65706 (November 23, 2007); *Notice of Final Results of Antidumping Duty Changed Circumstances Review and Revocation of Order In Part: Certain Corrosion-Resistant Carbon Steel Flat Products from Germany,* 71 FR 66163 (November 13, 2006); *Notice of Final Results of Antidumping Duty Changed Circumstances Reviews and Revocation of Orders in Part: Certain Corrosion-Resistant Carbon Steel Flat Products from Canada and Germany,* 71 FR 14498 (March 22, 2006); and *Notice of Final Results of Antidumping Duty Changed Circumstances Review, and Determination to Revoke Order in Part: Certain Cased Pencils from the People's Republic of China,* 68 FR 62428 (November 4, 2003).

[12] Submissions of rebuttal factual information must comply with 19 CFR 351.301(b)(2); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

[13] *See Temporary Rule*.

[14] *See* 19 CFR 351.216(e).

[15] As noted above, certain unliquidated entries are currently enjoined from liquidation by litigation, and parties may submit comments relating to Commerce's treatment of such entries.

Dated: December 19, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–28101 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Limitation of Duty-Free Imports of Apparel Articles Assembled in Haiti Under the Caribbean Basin Economic Recovery Act (CBERA), as Amended by the Haitian Hemispheric Opportunity Through Partnership Encouragement Act (HOPE)

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notification of Annual Quantitative Limit on Imports of Certain Apparel from Haiti.

SUMMARY: CBERA, as amended, provides duty-free treatment for certain apparel articles imported directly from Haiti. One of the preferences is known as the ''value-added'' provision, which requires that apparel meet a minimum threshold percentage of value added in Haiti, the United States, and/or certain beneficiary countries. The provision is subject to a quantitativ elimitation, which is calculated as a percentage of total apparel imports into the United States for each 12-month period. For the period from December 20, 2022 through December 19, 2023, the quantity of imports eligible for preferential treatment under the value-added provision is 412,506,163 square meters equivalent.

DATES: The new limitations become applicable December 20, 2022.

FOR FURTHER INFORMATION CONTACT: Laurie Mease, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–2043.

SUPPLEMENTARY INFORMATION:

Authority: Section 213A of the Caribbean Basin Economic Recovery Act (19 U.S.C. 2703a) (''CBERA''), as amended; and as implemented by Presidential Proc. No. 8114, 72 FR 13655 (March 22, 2007), and No. 8596, 75 FR 68153 (November 4, 2010).

Background: Section 213A(b)(1)(B) of CBERA, as amended (19 U.S.C. 2703a(b)(1)(B)), outlines the requirements for certain apparel articles imported directly from Haiti to qualify for duty-free treatment under a ''value-added'' provision. In order to qualify for duty-free treatment, apparel articles must be wholly assembled, or knit-to-shape, in Haiti from any combination of fabrics, fabric components, components knit-to-shape, and yarns, as long as the sum of the cost or value of materials produced in Haiti or one or more beneficiary countries, as described in CBERA, as amended, or any combination thereof, plus the direct costs of processing operations performed in Haiti or one or more beneficiary countries, as described in CBERA, as amended, or any combination thereof, is not less than an applicable percentage of the declared customs value of such apparel articles. Pursuant to CBERA, as amended, the applicable percentage for the period December 20, 2022 through December 19, 2023, is 60 percent.

For every twelve-month period following the effective date of CBERA, as amended, duty-free treatment under the value-added provision is subject to a quantitative limitation. CBERA, as amended, provides that the quantitative limitation will be recalculated for each subsequent 12-month period. Section 213A(b)(1)(C) of CBERA, as amended (19 U.S.C. 2703a(b)(1)(C)), requires that, for the twelve-month period beginning on December 20, 2022, the quantitative limitation for qualifying apparel imported from Haiti under the value-added provision will be an amount equivalent to 1.25 percent of the aggregate square meter equivalent of all apparel articles imported into the United States in the most recent 12-month period for which data are available. The aggregate square meters equivalent of all apparel articles imported into the United States is derived from the set of Harmonized System lines listed in the Annex to the World Trade Organization Agreement on Textiles and Clothing (''ATC''), and the conversion factors for units of measure into square meter equivalents used by the United States in implementing the ATC.

For purposes of this notice, the most recent 12-month period for which data are available as of December 20, 2022 is the 12-month period ending on October 31, 2022. Therefore, for the one-year period beginning on December 20, 2022 and extending through December 19, 2022, the quantity of imports eligible for preferential treatment under the value-added provision is 412,506,163 square meters equivalent. Apparel articles entered in excess of these quantities will be subject to otherwise applicable tariffs.

Jennifer Knight,

Deputy Assistant Secretary for Textiles, Consumer Goods, Materials, Critical Minerals and Metals.

[FR Doc. 2022–28047 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Workplace Violence Prevention and Response Forms

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before February 27, 2023.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648-xxxx in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Dr. Lisa Charles, Acting Director, Workplace Violence Prevention and Response, (202) 236–9672, and *lisa.charles@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for a new information collection.

This information collection will be used to document elements of the

sexual assault/sexual harassment (SASH) response and/or reporting process and comply with procedures set up to effectively manage National Oceanic and Atmospheric Administration (NOAA), Workplace Violence Prevention and Response (WVPR). Under 33 U.S.C. 894, NOAA is required to establish a mechanism by which sexual assault and sexual harassment can be reported on a Restricted and Unrestricted basis. Further, Congress directs NOAA to reference Department of Defense (DoD) policy and procedures in the standup of our SASH response program. WVPR requires various Intake forms to document a victim's election of a Restricted or Unrestricted Report of sexual assault or sexual harassment, as well as document that the details of each reporting option have been properly communicated with the victim. WVPR has modeled its forms after the DoD sexual assault/sexual harassment forms in accordance with guidance by Congress. NOAA may also use this collection to survey federal employees, contractors, affiliates, interns, volunteers, or other individuals who work in or visit NOAA-occupied facilities, vessels, or aircraft to determine their perceptions of incidents of SASH, pursuant to NOAA Administrative Order (NAO) 202–1106, Section 5.01e.

II. Method of Collection

Information on this form will be collected using a paper format or electronically and requires the victim's signature either by ink pen or CAC.

III. Data

OMB Control Number: 0648–XXXX.

Form Number(s): None.

Type of Review: Regular submission, new information collection.

Affected Public: Individuals employed by NOAA including affiliates and contractors.

Estimated Number of Respondents: 500.

Estimated Time per Response: 60 minutes.

Estimated Total Annual Burden Hours: 500.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Voluntary.

Legal Authority: 33 U.S.C. 894.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

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

[FR Doc. 2022–28149 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Pribilof Islands, Taking for Subsistence Purposes

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 10, 2022 (87 FR 48648) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Pribilof Islands, Taking for Subsistence Purposes.

OMB Control Number: 0648–0699.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 2.

Average Hours per Response: Subsistence harvest and hunt reports submitted via email estimated to take 40 hours per response for each respondent. The St. George Island Traditional Council submits two reports annually and the Aleut Community of St. Paul Island submits three reports annually.

Total Annual Burden Hours: 200.

Needs and Uses: The subsistence use of northern fur seals is cooperatively managed by the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS) and the Tribal Governments of St. Paul and St. George Islands under § 119 of the Marine Mammal Protection Act, 16 U.S.C. 1388 (MMPA) and governed by regulations found in 50 CFR part 216 subpart F, Taking for Subsistence Purposes under the Fur Seal Act (16 U.S.C. 1155). The regulations, laws, and cooperative agreements are focused on conserving northern fur seals through cooperative effort and consultation regarding effective management of human activities related to the subsistence harvests of northern fur seals and Steller sea lions. In 2014, NMFS obtained a collection of information control number (79 FR 65327; November 4, 2014), reviewed the control number in 2017 (82 FR 51218; November 3, 2017), updated the control number in 2019 (84 FR 52372; October 2, 2019, and corrected in 2020 (85 FR 15948; March 20, 2020).

This an information collection for the annual subsistence use male northern fur seals by Alaska Natives (Pribilovians) residing in the communities of St. Paul and St. George, Alaska (Pribilof Islands) under 50 CFR 216 part 216 subpart F. NMFS established regulations regarding the maximum levels for the annual subsistence needs of the Pribilovians after direct consultation with the Tribal Governments of St. Paul and St. George Islands in Alaska and their respective local Native corporations (Tanadgusix and Tanaq). NMFS regulation creates independent northern fur seal subsistence seasons on St. Paul and St. George islands to include male fur seals less than 7 years old, limits on accidental mortality of female northern

fur seals, monitoring and reporting through co-management processes established under their respective cooperative agreements. The regulations at 50 CFR 216.72 state that Pribilovians are responsible for reporting their subsistence needs and actual level of subsistence take. NMFS receives electronic copies of the northern fur seal subsistence use reports from the tribal governments of St. Paul and St. George annually. NMFS subsequently posts these reports online (*https://www.fisheries.noaa.gov/alaska/marine-mammal-protection/northern-fur-seal-subsistence-harvest-estimates-and-reports*) and includes the relevant data in the annual Alaska Marine Mammal Stock Assessment Report. The only change requested is the changing of the title of the information collection to Pribilof Islands, Taking for Subsistence Purposes.

Affected Public: Individuals or households, and State, Local or Tribal Government.

Frequency: Annual.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: Fur Seal Act (16 U.S.C. 1155).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0699.

Sheleen Dumas,

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

[FR Doc. 2022–28100 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Resident Perceptions of Offshore Wind Energy Development Off the Oregon Coast

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on October 3, 2022 (87 FR 59781) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Resident Perceptions of Offshore Wind Energy Development off the Oregon Coast.

OMB Control Number: 0648–0744.

Form Number(s): None.

Type of Request: Reinstatement with change.

Number of Respondents: 4,617.

Average Hours per Response: Focus groups: 1 hour; Questionnaire: 20 minutes.

Total Annual Burden Hours: 1,571.

Needs and Uses: Pursuant to E.O. 14057 (Executive Order on Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability), the Outer Continental Shelf Land Act, the National Environmental Policy Act, and the Coastal Zone Management Act, this request is for a reinstatement of an information collection with change. This information collection will focus on a different geographical location (the coast of Oregon) and include focus groups, which will help guide any revisions necessary to the survey instrument.

The BOEM Pacific OCS Region has an active Renewable Energy Program and is currently processing wind and wave energy lease requests. Due to the relatively steep continental slope and deep water off the West Coast, different types of offshore renewable energy technologies have been proposed for the Pacific Region than for the Atlantic Region. Outside of official public engagement forums, preferences about offshore wind energy development generally remain unknown for members of the public, as well as for groups who may not perceive themselves as stakeholders. Failure to gain the perspective of communities regarding potential benefits or impacts is problematic, particularly when latent stakeholders to local projects emerge late in the planning process.

The National Ocean Service (NOS) proposes to collect data on the opinions, values, and attitudes of Oregon Coast residents relative to offshore wind energy development. Respondents (age 18 years and older) will be randomly sampled from households in seven coastal counties. This information will be used by BOEM, NOAA, and others to understand what is important to communities; understand how differing values and perceptions across communities influence local receptivity to proposed development; and improve communication efforts targeted to residents, enabling agencies to more effectively and efficiently direct outreach and community inclusion activities. Additionally, NOAA has a vested interest in offshore wind energy development, from many perspectives, including as it relates to the resilience, well-being, and sustainability of coastal communities.

Affected Public: Individuals or households.

Frequency: This is a one-time information collection for this region, although the collection may be deployed to other regions in the future.

Respondent's Obligation: Voluntary.

Legal Authority: NOAA's Programmatic Authority—Integrated Coastal and Ocean Observation System Act (33 U.S.C. 3601 *et seq.*); BOEM's Programmatic Authority—Outer Continental Shelf Lands Act (43 U.S.C. 1346).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and

entering either the title of the collection or the OMB Control Number 0648–0744.

Sheleen Dumas,

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

[FR Doc. 2022–28148 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–JS–P

DEPARTMENT OF COMMERCE

National Technical Information Service

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Limited Access Death Master File Certification Form (Certification Form)

AGENCY: National Technical Information Service (NTIS), Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before February 27, 2023.

ADDRESSES: Interested persons are invited to submit written comments to Daniel Ramsey, Supervisory Program Manager, Office of Program Management, National Technical Information Service, Department of Commerce, at *dramsey@ntis.gov* or at *PRAcomments@doc.gov.* Please reference OMB Control Number 0692–0013 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Daniel Ramsey, Supervisory Program Manager, Office of Program Management, National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 by email: *dramsey@ntis.gov* or telephone: 703–605–6703.

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for extension of an existing information collection.

NTIS issued a final rule establishing a program through which persons may become eligible to obtain access to Death Master File (DMF) information about an individual within three years of that individual's death (81 FR 34882, June 1, 2016). The final rule was promulgated under Section 203 of the Bipartisan Budget Act of 2013, Public Law 113–67 (Act). The Act prohibits the Secretary of Commerce (Secretary) from disclosing DMF information during the three-year period following an individual's death (Limited Access DMF), unless the person requesting the information has been certified to access the Limited Access DMF pursuant to certain criteria in a program that the Secretary establishes. The Secretary delegated the authority to carry out Section 203 to the Director of NTIS.

The final rule requires that a Person seeking access to the Limited Access Death Master File establish a legitimate fraud prevention interest or legitimate business purpose pursuant to a law, governmental rule, regulation, or fiduciary duty. The Certification Form collects information that NTIS will use to evaluate whether the respondent qualifies to receive the Limited Access Death Master File under the rule.

II. Method of Collection

Electronic.

III. Data

OMB Control Number: 0692–0013.

Form Number(s): NTIS FM161.

Type of Review: Regular submission (extension of approved information collection.)

Affected Public: Individuals or households.

Estimated Number of Respondents: 260.

Estimated Time per Response: 3 hours.

Estimated Total Annual Burden Hours: 780.

Estimated Total Annual Cost to Public: $888,160.

Respondent's Obligation: Voluntary.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

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

[FR Doc. 2022–28120 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–04–P

DEPARTMENT OF COMMERCE

National Technical Information Service

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Limited Access Death Master File Accredited Conformity Assessment Body Application for Firewalled Status (Firewalled Status Application Form)

AGENCY: National Technical Information Service (NTIS), Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before February 27, 2023.

ADDRESSES: Interested persons are invited to submit written comments to Daniel Ramsey, Supervisory Program Manager, Office of Program Management, National Technical Information Service, Department of Commerce, at *dramsey@ntis.gov* or at *PRAcomments@doc.gov.* Please reference OMB Control Number 0692–0015 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Daniel Ramsey, Supervisory Program Manager, Office of Program Management, National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 by email: *dramsey@ntis.gov* or telephone: 703–605–6703.

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for extension of an existing information collection.

NTIS issued a final rule establishing a program through which persons may become eligible to obtain access to Death Master File (DMF) information about an individual within three years of that individual's death (81 FR 34882, June 1, 2016). The final rule was promulgated under section 203 of the Bipartisan Budget Act of 2013, Public Law 113–67 (Act). The Act prohibits the Secretary of Commerce (Secretary) from disclosing DMF information during the three-year period following an individual's death (Limited Access DMF), unless the person requesting the information has been certified to access the Limited Access DMF pursuant to certain criteria in a program that the Secretary establishes. The Secretary delegated the authority to carry out Section 203 to the Director of NTIS.

The final rule requires that, in order to become certified, a Person must submit a written attestation from an ''Accredited Conformity Assessment Body'' (ACAB), as defined in the final rule, that such Person has information security systems, facilities and procedures in place to protect the security of the Limited Access DMF, as required under Section 1110.102(a)(2) of the final rule. A Certified Person also must provide a new written attestation periodically for renewal of its certification as specified in the final rule. The ACAB must be independent of the Person or Certified Person seeking certification, unless it is a conformity assessment body which qualifies for ''firewalled status'' pursuant to Section 1110.502 of the final rule.

The Firewalled Status Application Form collects information that NTIS will use to evaluate whether the respondent qualifies for ''firewalled status'' under the rule, and, therefore, can provide a written attestation in lieu of an independent ACAB's attestation. This information includes specific requirements of Section 1110.502(b) of the final rule, which the respondent ACAB must certify are satisfied, and the provision of specific information by the respondent ACAB, such as the identity of the Person or Certified Person that would be the subject of the attestation and the basis upon which the certifications were made.

II. Method of Collection

Electronic.

III. Data

OMB Control Number: 0692–0015.

Form Number(s): NTIS FM101.

Type of Review: Regular submission (extension of approved information collection.)

Affected Public: Individuals or households.

Estimated Number of Respondents: 260.

Estimated Time per Response: 60 minutes.

Estimated Total Annual Burden Hours: 65.

Estimated Total Annual Cost to Public: $39,910.

Respondent's Obligation: Voluntary.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

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

[FR Doc. 2022–28124 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–04–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Secrecy and License to Export

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0034 Secrecy and License to Export. The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before February 27, 2023.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Justin Isaac, Office of the Chief Administrative 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 Parikha Mehta, Senior Legal Advisor, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–3248; or by email at *parikha.mehta@uspto.gov* with ''0651–0034 comment'' in the subject line. Additional information about this information collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

In the interest of national security, patent laws and regulations place certain limitations on the disclosure of information contained in patents and patent applications and on the filing of applications for patents in foreign countries.

A. Secrecy Orders

Whenever the publication or disclosure of an invention by the publication of an application or by the granting of a patent is, in the opinion of the head of an interested Government agency, determined to be detrimental to national security, the Commissioner for Patents at the United States Patent and Trademark Office (USPTO) must issue a secrecy order and withhold the publication of a patent application and the grant of a patent for such period as the national interest requires. A patent will not be issued on the application, nor will the application be published, as long as the secrecy order is in force. If a secrecy order is applied to an international application, the application will not be forwarded to the International Bureau as long as the secrecy order is in effect.

The Commissioner for Patents can issue three types of secrecy orders, each of a different scope. The first type, Secrecy Order and Permit for Foreign Filing in Certain Countries, is intended to permit the widest utilization of the technical data in the patent application while still controlling any publication or disclosure that would result in an unlawful exportation. The second type, the Secrecy Order and Permit for Disclosing Classified Information, is to treat classified technical data presented in a patent application in the same manner as any other classified material. The third type of secrecy order is used where the other types of orders do not apply, including orders issued by direction of agencies other than the Department of Defense.

Under the provision of 35 U.S.C. 181, a secrecy order remains in effect for a period of one year from its date of issuance. A secrecy order may be renewed for additional periods of not more than one year upon notice by a government agency that the national interest continues to so require. The applicant is notified of such renewal.

When the USPTO places a secrecy order on a patent application, the regulations authorize the applicant to petition the USPTO for permits to allow disclosure, modification, or rescission of the secrecy order, or to obtain a general or group permit. In each of these circumstances, the petition is forwarded to the appropriate defense agency for decision. Also, the Commissioner for Patents at the USPTO may rescind any order upon notification by the heads of the departments and the chief officers of the agencies who caused the order to be issued that the disclosure of the invention is no longer deemed detrimental to the national security.

Unless expressly ordered otherwise, action on the application and prosecution by the applicant will proceed during the time the application is under secrecy order to the point indicated in 37 CFR 5.3. See the Manual of Patent Examining Procedure (MPEP) Section 130 (9th ed., rev. 10.2019, June 2020). For example, prosecution of a national application under secrecy order may proceed only to the point where it is found to be in condition for allowance. See 37 CFR 5.3(c). Prosecution of international applications under secrecy order, on the other hand, will proceed only to the point before record and search copies would be transmitted to the international authorities or the applicant. See 37 CFR 5.3(d). National applications under secrecy order that come to a final rejection must be appealed or otherwise prosecuted to avoid abandonment. See 37 CFR 5.3(a). Appeals in such cases must be completed by the applicant. Unless specifically ordered by the Commissioner for Patents, these appeals will not be set for hearing until the secrecy order is removed. See id.

B. Foreign Filing License

In addition, this information collection covers information gathered with respect to foreign filing licenses. The filing of a patent application is considered a request for a foreign filing license. However, in some instances an applicant may need a license for filing patent applications in foreign countries prior to a filing in the USPTO or sooner than the anticipated licensing of a pending patent application.

For such circumstances, this information collection covers petitions for a foreign filing license either with or without a corresponding United States application. In addition, this information collection covers petitions to change the scope of a license and petitions for a retroactive license for instances when a patent application is filed through error in a foreign country without the appropriate filing license.

This information collection includes the information needed by the USPTO to review the various types of petitions regarding secrecy orders and foreign filing licenses. This collection of information is required by 35 U.S.C. 181–183 and 184–186 and administered by the USPTO through 37 CFR 5.1–5.5, 5.11–5.15, and 5.18–5.25.

II. Method of Collection

Electronically via the USPTO's patent electronic filing system, by mail, or by hand delivery to the USPTO.

III. Data

OMB Control Number: 0651–0034.

Forms: None.

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Respondent's Obligation: Required to obtain or retain benefits.

Estimated Number of Annual Respondents: 7,524 respondents.

Estimated Number of Annual Responses: 7,524 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately between 30 minutes (0.5 hours) and 4 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item to the USPTO.

Estimated Total Annual Respondent Burden Hours: 4,503 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $1,958,805.

TABLE 1—TOTAL BURDEN HOURS AND HOURLY COSTS TO PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents (a)	Responses per respondent (b)	Estimated annual responses (a) × (b) = (c)	Estimated time for response (hours) (d)	Estimated burden (hour/year) (c) × (d) = (e)	Rate [1] ($/hour) (f)	Estimated annual respondent cost burden (e) × (f) = (g)
1	Petition for Rescission of Secrecy Order.	10	1	10	3	30	$435	$13,050
2	Petition to Disclose or Modification of Secrecy Order.	10	1	10	2	20	435	8,700
3	Petition for General and Group Permits.	1	1	1	1	1	435	435
4	Petition for Expedited Handling of License (no corresponding application).	6,860	1	6,860	0.5	3,430	435	1,492,050
5	Petition for Expedited Handling of License (corresponding U.S. application).	294	1	294	0.5	147	435	63,945
6	Petition for Changing Scope of License.	3	1	3	0.5	2	435	870
7	Petition for Retroactive License.	196	1	196	4	784	435	341,040
	Totals	7,374		7,374		4,414		1,920,090

[1] 2021 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); pg. F–27. The USPTO uses the average billing rate for intellectual property attorneys in private firms which is $435 per hour. (*https://www.aipla.org/home/news-publications/economic-survey*).

TABLE 2—TOTAL BURDEN HOURS AND HOURLY COSTS TO INDIVIDUAL AND HOUSEHOLD RESPONDENTS

Item No.	Item	Estimated annual respondents (a)	Responses per respondent (b)	Estimated annual responses (a) × (b) = (c)	Estimated time for response (hours) (d)	Estimated burden (hour/year) (c) × (d) = (e)	Rate [2] ($/hour) (f)	Estimated annual respondent cost burden (e) × (f) = (g)
4	Petition for Expedited Handling of License (no corresponding application).	140	1	140	0.5	70	$435	$30,450
5	Petition for Expedited Handling of License (corresponding U.S. application).	6	1	6	0.5	3	435	1,305
7	Petition for Retroactive License.	4	1	4	4	16	435	6,960
	Totals	150		150		89		38,715

Estimated Total Annual Respondent Non-hourly Cost Burden: $1,477,829.

There are no maintenance costs, capital start-up costs, or recordkeeping costs associated with this information collection. However, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of filing fees ($1,477,135) and postage ($694), is $1,477,829.

Filing Fees

The items with filing fees are listed in the table below.

TABLE 3—FILING FEES

IC No.	Item	Responses (a)	Filing fee ($) (b)	Total non-hour cost burden (a) × (b) = (c)
4	Petition for Expedited Handling of License (no corresponding application) (undiscounted entity)	5,600	$220	$1,232,000
4	Petition for Expedited Handling of License (no corresponding application) (small entity)	1,260	110	138,600
4	Petition for Expedited Handling of License (no corresponding application) (micro entity)	140	55	7,700
5	Petition for Expedited Handling of License (corresponding U.S. application) (undiscounted entity)	240	220	52,800
5	Petition for Expedited Handling of License (corresponding U.S. application) (small entity)	54	110	5,940
5	Petition for Expedited Handling of License (corresponding U.S. application) (micro entity)	6	55	330
6	Petition for Changing Scope of License (undiscounted entity)	1	220	220
6	Petition for Changing Scope of License (small entity)	1	110	110
6	Petition for Changing Scope of License (micro entity)	1	55	55
7	Petition for Retroactive License (undiscounted entity)	160	220	35,200
7	Petition for Retroactive License (small entity)	36	110	3,960

[2] Ibid.

TABLE 3—FILING FEES—Continued

IC No.	Item	Responses (a)	Filing fee ($) (b)	Total non-hour cost burden (a) × (b) = (c)
7	Petition for Retroactive License (micro entity)	4	55	220
	Totals	7,503		1,477,135

Postage

The USPTO estimates that 99% of the petitions in this information collection are submitted electronically, by facsimile, or hand carried because of the quick turnaround required, and only 1% of the 7,524 petitions will be submitted in the mail. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be $9.25 and that approximately 75 submissions will be mailed to the USPTO per year. Therefore, the USPTO estimates that postage costs in this collection will be $694.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Adminstrative Officer, United States Patent and Trademark Office.

[FR Doc. 2022–28151 Filed 12–23–22; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Renew Collection 3038–0107, Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is announcing an opportunity for public comment on the renewal of collection of certain information by the Commission's Office of Customer Education and Outreach (''OCEO''). Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed or renewal of a collection of information and to allow 60 days for public comment. The Commission is soliciting comments for the renewal of its generic information collection that will help the CFTC satisfy responsibilities under the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''), found in Section 748 of the Dodd-Frank Act. The generic information collection will provide the OCEO a means to gather qualitative consumer and stakeholder feedback in an efficient, timely manner to facilitate service delivery.

DATES: Comments must be submitted on or before February 27, 2023.

ADDRESSES: You may submit comments, identified by ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery,'' and Collection Number 3038–0107, by any of the following methods:

- The Agency's website, at *https://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Dan Rutherford, Associate Director, Office of Customer Education and Outreach, Commodity Futures Trading Commission, 1155 21st Street NW, Washington, DC 20581, (202) 418–6623; email: *drutherford@cftc.gov,* and refer to OMB Control No. 3038–0107.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (''OMB'') for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below. 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.

Title: Generic Clearance for Collection of Qualitative Feedback on Agency Service Delivery (OMB Control No. 3038–0107). This is a request for an extension of a currently approved information collection.

Abstract: In accordance with section 748 of the Dodd-Frank Act, the OCEO anticipates undertaking a variety of service delivery focused activities over the next few years that include consumer outreach and information-sharing with stakeholders which are responsive to stakeholders' needs and sensitive to changes in the market. The proposed information collection activity will use similar methods for information collection or otherwise share common elements, and provide a means to gather qualitative customer and stakeholder feedback in an efficient, timely manner. By qualitative feedback we mean information that provides useful information on perceptions and opinions. The solicitation of information on delivery of consumer services will address such areas as appropriate messages, effective message delivery methods, effective event outreach tactics and characteristics, new outreach program ideas and content, and current consumer beliefs, psychographics and social norms that will assist the agency in developing outreach and communications campaigns. Since these systems will use similar methods for information collection or otherwise share common elements, the OCEO is proposing a generic clearance for this process, which will allow the OCEO to implement these systems and meet the obligations of the PRA without the delays of the normal clearance process. Collection methods may include focus groups and surveys as well as other relevant collection methods that meet the conditions appropriate for a generic clearance as outlined below. The OCEO will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondent, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the Commission (if released, the Commission must indicate the qualitative nature of the information);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

With respect to the collection of information, the Commission invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burdens of collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

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 *https://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 Information Collection Request 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.

Burden Statement: The respondent burden for this collection is estimated to be as follows:

Type of Review: Generic Clearance Request.

Affected Public/Entities: Individuals and Households, Businesses and Organization, State, Local or Tribal governments.

Respondent's Obligation: Voluntary.

Estimated Number of Respondents Annually: 17,279.

Frequency of Collection: Once per request.

Average Time per Response: 0.29 hours or approximately 17 minutes.

Estimated Total Annual Burden Hours Requested: 4,000 hours (rounded).

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: December 20, 2022.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2022–28050 Filed 12–23–22; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 145.9.

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2022–0086]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) requests the extension of the Office of Management and Budget's (OMB's) approval of an existing information collection titled ''Truth in Savings (Regulation DD)'' approved under OMB Number 3170–0004.

DATES: Written comments are encouraged and must be received on or before January 26, 2023 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open

for Public Comments'' or by using the search function. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Anthony May, Paperwork Reduction Act Officer, at (202) 435–7278, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Truth in Savings (Regulation DD).

OMB Control Number: 3170–0004.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Private sector: businesses or other for-profits institutions.

Estimated Number of Respondents: 171.

Estimated Total Annual Burden Hours: 561,632.

Abstract: Consumers rely on the disclosures required by the Truth in Savings Act (TISA) and Regulation DD to facilitate informed decision-making regarding deposit accounts offered at depository institutions. Without this information, consumers would be severely hindered in their ability to assess the true costs and terms of the deposit accounts offered. Federal agencies and private litigants use these records to ascertain whether accurate and complete disclosures of depository accounts have been provided to consumers. This information also provides the primary evidence of law violations in TISA enforcement actions brought by the Bureau. Without the Regulation DD recordkeeping requirement, the Bureau's ability to enforce TISA would be significantly impaired.

Request for Comments: The Bureau published a 60-day **Federal Register** notice on October 4, 2022 (87 FR 60136) under Docket Number: CFPB–2022–0065. The Bureau is publishing this notice and soliciting comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2022–28044 Filed 12–23–22; 8:45 am]

BILLING CODE 4810–AM–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; Application Package for External Reviewer Application

AGENCY: The Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to revise an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by February 27, 2023.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) Electronically through *www.regulations.gov* (preferred method).

(2) By mail sent to: AmeriCorps, Attention Danielle Horetsky, 250 E Street SW, Washington, DC 20525.

(3) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (2) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

Comments submitted in response to this notice may be made available to the public through *regulations.gov*. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Danielle Horetsky, 202–606–3863, or by email at *DHoretsky@cns.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: External Reviewer Application Instructions.

OMB Control Number: 3045–0090.

Type of Review: Revision.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 500 Respondents.

Total Estimated Number of Annual Burden Hours: 250.

Abstract: The External Reviewer Application is used by individuals who wish to serve as External Reviewers for AmeriCorps when external reviewers are needed to review grant applications. The information collected will be used by AmeriCorps to select review participants for each grant competition. The information is collected electronically using AmeriCorps' web-based system. AmeriCorps seeks to revise the current information collection. AmeriCorps also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on February 28, 2023.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to

generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on *regulations.gov*.

Lisa Bishop,

Director, Office of Grant Administration.

[FR Doc. 2022–28070 Filed 12–23–22; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2022–HQ–0011]

Proposed Collection; Comment Request

AGENCY: Department of the Air Force, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Air Force announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 27, 2023.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to 2020 Space Force Pentagon, Rm 5C345, Washington, DC 20330–1670, MSgt Nestor Bauer, 703–697–4299.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: USSF DEIA Survey; OMB Control Number 0701–DEIA.

Needs and Uses: This survey is designed to tie into the requirements in Executive Order 14035 and will help the United States Space Force S2 Intelligence, Surveillance, and Reconnaissance Enterprise identify current attitudes, viewpoints, and overall social climate with respect to diversity, inclusion, equity, and accessibility. This information will assist to inform development of DEIA training, strategy, and communications planning to support DEIA efforts and initiatives.

Affected Public: Individuals or households.

Annual Burden Hours: 97.

Number of Respondents: 305.

Responses per Respondent: 1.

Annual Responses: 305.

Average Burden per Response: 19 minutes.

Frequency: Annually.

Dated: December 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–28067 Filed 12–23–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID USAF–2022–HQ–0010]

Proposed Collection; Comment Request

AGENCY: Department of the Air Force, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Air Force/A4C announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 27, 2023.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to AFMC/AFLCMC/HIBD, 201 East Moore Drive, Bldg. 856 Rm.

208, MAFB-Gunter Annex, Alabama, 36114–3005, Ms. Tiffany J. Fitzgerald, 334–465–5814.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Fire and Emergency Services—Information Management System (FES–IMS) Electronic Records; OMB Control Number 0701–FESR.

Needs and Uses: For Fire and Emergency Services—Information Management System (FES–IMS) users, PII data is required to establish accounts. Users are Fire Department support personnel to include: Air Force Active Duty, Air National Guard, Air Force Reserve personnel, Air Force Department of Defense Civilians, and Air Force Civil Engineering contractors. Air Force DoD Civilians and Contracted employees at OCONUS locations may include foreign nationals employed at U.S. Military facilities. Data collected supports the daily operations of Air Force Fire Departments and Emergency Dispatch Centers for personnel tracking, shift scheduling, training requirements tracking, and documenting after-action reports of an incident. This information is critical to protect installation resources, equipment, and personnel that require emergency services.

Affected Public: Individuals or households.

Annual Burden Hours: 500.

Number of Respondents: 2,000.

Responses per Respondent: 1.

Annual Responses: 2,000.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

Dated: December 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–28048 Filed 12–23–22; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0086]

Submission for OMB Review; Comment Request

AGENCY: Defense Security Cooperation Agency (DSCA), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 26, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: The GlobalNET Collection; OMB Control Number 0704–0558.

Type of Request: Revision.

Number of Respondents: 130.

Responses per Respondent: 1.

Annual Responses: 130.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 11.

Needs and Uses: The purpose of the GlobalNET system is to provide a collaborative social networking environment/capability where students, alumni, faculty, partners, and other community members and subject matter experts can find relevant and timely information about pertinent subject matter experts and conduct required training. GlobalNET also collects information on students in order to allow regional center personnel to manage students while enrolled at regional centers.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–28039 Filed 12–23–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2022–OS–0141]

Proposed Collection; Comment Request

AGENCY: Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Logistics Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 27, 2023.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions

from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Logistics Agency, DLA Human Capital Program Development, 8725 John J. Kingman Road, Fort Belvoir, VA 22060–6220, ATTN: Shannon Lewis, or call 571–767–0956.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; And OMB Number: DLA Culture/Climate Survey; OMB Control Number 0704–0575.

Needs and Uses: The information collection requirement is necessary to obtain and record the perceptions of DLA employees regarding the organizational culture and climate. The DLA Culture/Climate Survey standardizes how organizational culture/climate is measured across the DLA enterprise, focuses leadership attention on culture/climate, and drives actions to improve the overall culture/climate and DLA organizational performance.

Affected Public: Individuals or households.

Annual Burden Hours: 645.

Number of Respondents: 860.

Responses per Respondent: 1.

Annual Responses: 860.

Average Burden per Response: 45 minutes.

Frequency: Biennially.

Respondents are Foreign Nationals employed by DLA. The DLA Culture/Climate Survey provides a confidential mechanism for employees to share feedback on their work environment, resulting in opportunities for DLA employees and leaders to engage in thoughtful, data-driven discussions that lead to informed action and improve the DLA collective performance.

Dated: December 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–28054 Filed 12–23–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0118]

Submission for OMB Review; Comment Request

AGENCY: Defense Counterintelligence and Security Agency (DCSA), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 26, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: FOCI Outside Director/Proxy Holder Nomination Questionnaires; OMB Control Number 0705–0005.

Type of Request: Revision.

Number of Respondents: 250.

Responses per Respondent: 1.

Annual Responses: 250.

Average Burden per Response: 45 minutes.

Annual Burden Hours: 188.

Needs and Uses: This information collection is necessary for DCSA to provide proper monitoring and oversight of companies with Foreign Ownership, Control, or Influence (FOCI) while those companies provide services on a U.S. government contract. In order to mitigate foreign ownership risks, DCSA approves the nomination of Outside Director/Proxy Holder(s) (OD/PH) for specified companies when the mitigation strategy requires their appointment. The OD/PH will be a cleared U.S. citizen, disinterested in the company and its shareholder, who can exercise management prerogative to ensure the foreign owner is effectively insulated from controlling or influencing the management or business of the cleared company in a manner that could affect its performance on classified contracts. DCSA must collect information from both the company officials nominating individuals for the OD/PH role, as well as the nominees themselves. This information is necessary to verify that all nominated OD/PH are capable of performing their duties effectively at the time of nomination and understand their responsibility in serving an OD/PH role. It also helps DCSA ensure that the FOCI boards are effective in fulfilling their national security and fiduciary responsibilities while under FOCI mitigation. DCSA authority for this information collection can be found in 32 CFR 117, the National Industrial Security Program Operating Manual Rule, which, in part, describes how cleared contractors under FOCI must operate to possess a facility clearance.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–28040 Filed 12–23–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0096]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 26, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for the Review of Discharge or Dismissal from the Armed Forces of the United States; DD Form 293; OMB Control Number 0704–0004.

Type of Request: Extension.

Number of Respondents: 2,827.

Responses per Respondent: 1.

Annual Responses: 2,827.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 1,413.5.

Needs and Uses: Under Title 10 U.S.C. 1553 and DoD Directive 1332.41, ''Boards for the Correction of Military Records and Discharge Review Board (DRBs),'' former service members who received an administrative discharge have the right to appeal the characterization or reason for separation provided they do so within 15 years from the date of separation. The DD Form 293, ''Application for Review of Discharge or Separation from the Armed Forces of the United States,'' is the form that allows former Service members to explain the reasons for the alleged error and designate legal counsel, and provides DRBs necessary information to process requests. This information collection is needed to provide Service members a method to present to their respective Military Department Discharge Review Boards their reason/justification for a discharge upgrade, as well as providing the Military Departments with the basic data needed to process the appeal. The primary purpose of this information is to identify the arguments of the respondents and justifications for requested relief and secure their Official Military Personnel Files from the National Records Center. In addition, the collection allows the respondent to explain the reasons for the alleged error or injustice, designate counsel of choice, select the method of hearing desired, and request a records review or personal hearing.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 20, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–28037 Filed 12–23–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0159]

Agency Information Collection Activities; Comment Request; Foreign Gifts and Contracts Disclosures

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before February 27, 2023.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0159. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave, SW, LBJ, Room 6W203, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 377–4018.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate;

(4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Foreign Gifts and Contracts Disclosures.

OMB Control Number: 1845–NEW.

Type of Review: New ICR.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 2,043.

Total Estimated Number of Annual Burden Hours: 20,430.

Abstract: Federal Student Aid (FSA) is requesting a new information collection to collect the required information from institutions regarding foreign gifts and contracts as specified in the Higher Education Act of 1965 (HEA), as amended. Section 117 of the HEA, codified at 20 U.S.C. 1011f, provides that institutions of higher education must file a disclosure report with the Secretary of Education on January 31 or July 31, whichever is sooner, under certain circumstances.

In June of 2020, the U.S. Department of Education (ED) established a collection of information, Foreign Gifts and Contracts Disclosures, 1801–0006, through ED's Partner Enterprise Business Collaboration (PEBC) system. That collection is under an OMB control number for ED's Office of the General Counsel (OGC), which has worked closely with FSA in recent years with respect to administration of Section 117.

With this request for a new collection, the Department would be returning the collection of this information to FSA, which is the office with primary responsibility for the administration of Section 117 within the Department going forward. At present, the Department plans to continue to collect this data through its PEBC system. The specifics of this data collection will not change the current process or reporting.

Dated: December 21, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–28119 Filed 12–23–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0158]

Agency Information Collection Activities; Comment Request; Student Assistance General Provisions—Subpart J—Approval of Independently Administered Tests

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before February 27, 2023.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0158. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 377–4018.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Student Assistance General Provisions—Subpart J—Approval of Independently Administered Tests.

OMB Control Number: 1845–0049.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: Private Sector; Individuals or Households; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 67,989.

Total Estimated Number of Annual Burden Hours: 10,392.

Abstract: This request is for a revision of the approval for the reporting and recordkeeping requirements that are contained in the information collection 1845–0049 for Student Assistance General Provision in the regulations in Subpart J-Approval of Independently Administered Tests; Specification of Passing Score; Approval of State Process.

There are no forms or formats established by the Department for the reporting or recordkeeping requirements. These regulations govern the application for and approval of assessments by the Secretary by a private test publisher or State that are used to measure a student's skills and abilities. The administration of approved ATB tests may be used to determine a student's eligibility for assistance for the Title IV student financial assistance programs authorized under the Higher Education Act of 1965, as amended (HEA) when, among other conditions, the student does not have a high school diploma or its recognized equivalent.

Dated: December 21, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–28116 Filed 12–23–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection

AGENCY: U.S. Department of Energy, Office of the Under Secretary for Infrastructure.

ACTION: Notice and request for comment.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed emergency collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) for clearance, pursuant to the Paperwork Reduction Act of 1995.

DATES: Comments regarding this proposed information collection must be received on or before January 20, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, please advise the DOE Desk Officer at OMB of your intention to make a submission as soon as possible, listed in the following paragraph.

ADDRESSES: Written comments should be sent to:

DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 735 17th Street NW, Washington, DC 20503.

And to: U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585, Attn: Julius Goldberg-Lewis.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Julius Goldberg-Lewis, U.S. Department of Energy, 1000 Independence Ave. SW, Washington, DC 20585 by email at *julius.goldberg-lewis@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

This proposed emergency information collection request contains:

(1) *OMB No.:* New;

(2) *Information Collection Request Title:* Output and Outcome Metrics for Financial Assistance and Rebates;

(3) *Type of Request:* Emergency;

(4) *Purpose:* Given the historic level of investment represented by Infrastructure Investment and Jobs Act programs, it is incumbent on DOE to transparently track, report, and communicate the outcomes of DOE's financial assistance and rebate programs. Executive Order 14052 directs federal agencies to prioritize ''investing public dollars efficiently and equitably, working to avoid waste, and focusing on measurable outcomes for the American people.'' This guidance specifies the uniform collection, measurement, and reporting methodologies necessary for a set of key metrics that DOE can use to communicate the outcomes and outputs of funds awarded, ensuring consistency, transparency, and accountability to support Administration and program objectives. This Information Collection addresses a set of key cross-cutting metrics that will track across DOE programs to assess and communicate DOE's progress toward meeting key agency priorities, including creating quality jobs, supporting domestic manufacturing, increasing equity and justice, reducing greenhouse gas (GHG) emissions, and providing pathways to private sector uptake. The metrics will inform transparent and consistent reporting of the key metrics across DOE awards and will include project-level location data covering outcomes and outputs for specific communities, allowing DOE to better understand who is affected by DOE funded programs and how. This approach will enable DOE to report metrics at the agency, office, portfolio, and program levels and will provide data that can help evaluate the efficiency and equity of the programs, educate the design and implementation of future programs, and identify and address potential waste. DOE proposes to collect information through applications and supporting documents information necessary to determine that whether rebate applicants meet the specified statutory criteria to receive payments under the equipment rebate programs.

(5) *Annual Estimated Number of Respondents:* 59,625;

(6) *Annual Estimated Number of Total Responses:* 97,625;

(7) *Annual Estimated Number of Burden Hours:* 107,750;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $6,893,845;

(9) *Statutory Authority:* Section 646 DOE Organization Act {42 U.S.C. 7256}; Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6301–6308.

Signing Authority

This document of the Department of Energy was signed on December 20, 2022, by Kathleen Hogan, Principal Deputy Under Secretary for Infrastructure, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on December 21, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–28104 Filed 12–23–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10853–030]

Otter Tail Power Company; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-Capacity Amendment of Diversion Dam Reservoir.

b. *Project No:* 10853–030.

c. *Date Filed:* December 2, 2022.

d. *Applicant:* Otter Tail Power Company (licensee).

e. *Name of Project:* Otter Tail River Hydroelectric Project.

f. *Location:* The project is located on the Otter Tail River, in Otter Tail County, Minnesota. The project does not occupy federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a—825r.

h. *Applicant Contact:* Darin Solberg, Superintendent, PO Box 496, Fergus Falls, MN, 56538–0496, (218) 739–8157, *Dsolberg@otpco.com.*

i. *FERC Contact:* Margaret Noonan, (202) 502–8971, *Margaret.Noonan@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests: 30 days from the date of notice issuance.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–10853–030. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The applicant completed testing the use of stoplogs at the Hoot Lake development to resolve compliance with target water surface elevations at the Hoot Diversion reservoir. It has filed a non-capacity amendment to incorporate the permanent use of stoplogs in the culvert between the Hoot Diversion reservoir and Hoot Lake to maintain target water surface elevations required in Article 401.[1]

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

[1] The target impoundment surface elevation at the Hoot Diversion reservoir is 1,256.00 feet mean sea level.

Dated: December 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–28123 Filed 12–23–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC23–43–000.

Applicants: Eight Point Wind, LLC, Elk City Renewables II, LLC, Great Prairie Wind, LLC, Sac County Wind, LLC, Sholes Wind, LLC, Yellow Pine Solar, LLC, Emerald Breeze Funding, LLC, Elk City Sholes Holdings, LLC, Sac County Wind Holdings, LLC, NextEra Energy Partners Acquisitions, LLC

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Eight Point Wind, LLC, et al.

Filed Date: 12/19/22.

Accession Number: 20221219–5293.

Comment Date: 5 p.m. ET 1/9/23.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG23–37–000.

Applicants: Waco Solar, LLC.

Description: Waco Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 12/20/22.

Accession Number: 20221220–5127.

Comment Date: 5 p.m. ET 1/10/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2727–006; ER10–1451–008; ER10–1467–009; ER10–1469–009; ER10–1473–008; ER10–1474–008; ER10–1478–010; ER10–2687–008; ER10–2688–011; ER10–2689–011; ER10–2728–010; ER11–3907–002.

Applicants: The Toledo Edison Company, Green Valley Hydro, LLC, West Penn Power Company, The Potomac Edison Company, Monongahela Power Company, Pennsylvania Electric Company, Metropolitan Edison Company, Pennsylvania Power Company, The Cleveland Electric Illuminating Company, Ohio Edison Company, Jersey Central Power & Light, Allegheny Energy Supply Company, LLC.

Description: Triennial Market Power Analysis for Northwest Region of Allegheny Energy Supply Company, LLC, et al.
Filed Date: 12/16/22.
Accession Number: 20221216–5316.
Comment Date: 5 p.m. ET 2/14/23.
Docket Numbers: ER11–2447–005.
Applicants: Pacific Northwest Generating Cooperative, Inc.
Description: Triennial Market Power Analysis for Northwest Region of Pacific Northwest Generating Cooperative.
Filed Date: 12/20/22.
Accession Number: 20221220–5116.
Comment Date: 5 p.m. ET 2/20/23.
Docket Numbers: ER20–67–001; ER20–113–001; ER20–116–001.
Applicants: Evergy Metro, Inc., Evergy Missouri West, Inc., Evergy Kansas Central, Inc.
Description: Supplement to September 28, 2020 Notice of Change in Status of the Evergy MBR Sellers.
Filed Date: 12/19/22.
Accession Number: 20221219–5305.
Comment Date: 5 p.m. ET 1/9/23.
Docket Numbers: ER23–154–000.
Applicants: Carson Hybrid Energy Center LLC.
Description: Supplement to Carson Hybrid Energy Center LLC submits tariff filing Application for Market Based Rate Authority submitted for Carson Hybrid Energy Center LLC tariff filing.
Filed Date: 12/14/22.
Accession Number: 20221214–5237.
Comment Date: 5 p.m. ET 12/27/22.
Docket Numbers: ER23–277–001.
Applicants: Westlake US 2 LLC.
Description: Tariff Amendment: Amendment to Pending Filing in Docket ER23–277 to be effective 1/1/2023.
Filed Date: 12/20/22.
Accession Number: 20221220–5146.
Comment Date: 5 p.m. ET 1/3/23.
Docket Numbers: ER23–440–001.
Applicants: Southwest Power Pool, Inc.
Description: Tariff Amendment: 1518R24 Arkansas Electric Cooperative Corp NITSA NOA to be effective 11/1/2022.
Filed Date: 12/20/22.
Accession Number: 20221220–5141.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ER23–575–000.
Applicants: Valley Electric Association, Inc.
Description: § 205(d) Rate Filing: Annual TRBAA Filing for 2023 to be effective 1/1/2023.
Filed Date: 12/8/22.
Accession Number: 20221208–5018.
Comment Date: 5 p.m. ET 12/29/22.
Docket Numbers: ER23–672–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 4039 Ponderosa Wind II & SPS Facilities Service Agreement to be effective 2/19/2023.
Filed Date: 12/20/22.
Accession Number: 20221220–5103.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ER23–673–000.
Applicants: BHE Glacier Wind 1, LLC.
Description: § 205(d) Rate Filing: Revisions to MBR Tariffs to Reflect Mitigated Markets and Other Updates to be effective 11/9/2022.
Filed Date: 12/20/22.
Accession Number: 20221220–5126.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ER23–674–000.
Applicants: BHE Wind Watch, LLC.
Description: § 205(d) Rate Filing: Revisions to MBR Tariffs to Reflect Mitigated Markets and Other Updates to be effective 11/9/2022.
Filed Date: 12/20/22.
Accession Number: 20221220–5128.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ER23–675–000.
Applicants: BHE Rim Rock Wind, LLC.
Description: § 205(d) Rate Filing: Revisions to MBR Tariffs to Reflect Mitigated Markets and Other Updates to be effective 11/9/2022.
Filed Date: 12/20/22.
Accession Number: 20221220–5138.
Comment Date: 5 p.m. ET 1/10/23
Docket Numbers: ER23–676–000.
Applicants: BHE Power Watch, LLC.
Description: § 205(d) Rate Filing: Revisions to MBR Tariffs to Reflect Mitigated Markets and Other Updates to be effective 11/9/2022.
Filed Date: 12/20/22.
Accession Number: 20221220–5139.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ER23–677–000.
Applicants: BHE Glacier Wind 2, LLC.
Description: § 205(d) Rate Filing: Revisions to MBR Tariffs to Reflect Mitigated Markets and Other Updates to be effective 11/9/2022.
Filed Date: 12/20/22.
Accession Number: 20221220–5140.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ER23–678–000.
Applicants: The Narragansett Electric Company.
Description: § 205(d) Rate Filing: Re-Filing of Service Agmts and Amended Service Agmt Under Schedule 21–RIE to be effective 12/31/9998.
Filed Date: 12/20/22.
Accession Number: 20221220–5172.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ER23–679–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: § 205(d) Rate Filing: Amendment BQDM Energy Storage 12–20–2022 to be effective 11/1/2022.
Filed Date: 12/20/22.
Accession Number: 20221220–5193.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ER23–680–000.
Applicants: Sunfish Solar LLC.
Description: Petition for Limited Waiver, Motion to Consolidate Proceedings, and Request for Expedited Review of Sunfish Solar LLC.
Filed Date: 12/16/22.
Accession Number: 20221216–5318.
Comment Date: 5 p.m. ET 1/6/23.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES23–19–000.
Applicants: International Transmission Company.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of International Transmission Company.
Filed Date: 12/19/22.
Accession Number: 20221219–5294.
Comment Date: 5 p.m. ET 1/9/23.
Docket Numbers: ES23–20–000.
Applicants: ITC Midwest LLC.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of ITC Midwest LLC.
Filed Date: 12/19/22.
Accession Number: 20221219–5295.
Comment Date: 5 p.m. ET 1/9/23.
Docket Numbers: ES23–21–000.
Applicants: Michigan Electric Transmission Company, LLC.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Michigan Electric Transmission Company, LLC.
Filed Date: 12/20/22.
Accession Number: 20221220–5118.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ES23–22–000.
Applicants: ITC Great Plains, LLC.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of ITC Great Plains, LLC.
Filed Date: 12/20/22.
Accession Number: 20221220–5119.
Comment Date: 5 p.m. ET 1/10/23.
Docket Numbers: ES23–23–000.
Applicants: PJM Interconnection, L.L.C.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of PJM Interconnection, L.L.C.
Filed Date: 12/20/22.
Accession Number: 20221220–5131.
Comment Date: 5 p.m. ET 1/10/23.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/*

fercgensearch.asp) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at:*http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–28128 Filed 12–23–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ23–2–000]

City of Anaheim, California; Notice of Filing

Take notice that on November 29, 2022, City of Anaheim, California submits tariff filing: City of Anaheim 2023 Transmission Revenue Balancing Account Adjustment and Gross Load Update, to be effective January 1, 2023.

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.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on December 20, 2022.

Dated: December 20, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–28126 Filed 12–23–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0164; FRL–10521–01–OCSPP]

Datawiz Corporation, DMI and WIPRO; Transfer of Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces that pesticide and chemical related information submitted to the Environmental Protection Agency (EPA) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Toxic Substances Control Act (TSCA), including information that may have been claimed as Confidential Business Information (CBI) by the submitter, will be transferred to Datawiz Corporation and its subcontractors, DMI and WIPRO, in accordance with the CBI regulations governing the disclosure of potential CBI. Datawiz Corporation and its subcontractors, DMI and WIPRO, have been awarded a contract to perform work for the EPA Office of Chemical Safety and Pollution Prevention (OCSPP), and access to this information will enable Datawiz Corporation and its subcontractors, DMI and WIPRO, to fulfill the obligations of the contract.

DATES: Access to this information by Datawiz Corporation and its subcontractors, DMI and WIPRO, will begin on or before January 3, 2023 and is expected to continue during the term the contract.

FOR FURTHER INFORMATION CONTACT: William Northern, Information Technology and Resources Management Division (7502P), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1493 email address: *northern.william@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

This action applies to the public in general. As such, the Agency has not attempted to describe all the specific entities that may be affected by this action.

II. What action is the Agency taking?

Under EPA contract number GS–35F–0059S/BPA–68HERD22A0006, the contractor, Datawiz Corporation, and its subcontractors, DMI and WIPRO, will perform Information Technology Services to support OCSPP's Information Management Systems. These services will enhance the use of OCSPP chemical information and associated project and program plan through effective data management. This includes maintaining and equipping OCSPP with knowledge and tools that enable efficient analysis, assessment, evaluation, and decision-making, as well as managing the new development projects using an Agile Development methodology and CMMI Level III best practices.

OCSPP has determined that Datawiz Corporation and its subcontractors, DMI and WIPRO, requires access to all pesticide and chemical related information submitted to EPA under FIFRA, FFDCA and TSCA to perform successfully the duties specified under the contract. Some of this information may be claimed or determined to be CBI.

In accordance with the requirements of 40 CFR 2.307(h)(2), the contract with Datawiz Corporation and its subcontractors, DMI and WIPRO, prohibits the use of the information for

any purpose not specified in the contract; prohibits disclosure of the information to a third party without prior written approval from the Agency; and requires that each official and employee of the contractor and subcontractors sign an agreement to protect the information from unauthorized release and to handle it in accordance with applicable procedures and requirements associated with handling information that may be claimed or determined to be CBI (*i.e.,* pursuant to the FIFRA and TSCA Information Security Manuals and 40 CFR part 2). In addition, Datawiz Corporation, and its subcontractors, DMI and WIPRO, are required to submit for EPA approval a security plan detailing how information claimed or determined to be CBI will be secured and protected against unauthorized release or compromise. No information will be provided to Datawiz Corporation and its subcontractors, DMI and WIPRO, until the requirements in the approved security plan have been fully satisfied. Records of information provided to Datawiz Corporation and its subcontractors, DMI and WIPRO, will be maintained by the EPA Project Officers for this contract. All information supplied to Datawiz Corporation and its subcontractors, DMI and WIPRO, by EPA for use in connection with this contract will be returned to EPA when Datawiz Corporation and its subcontractors, DMI and WIPRO, have completed their work.

Access to this information, including any information that may be claimed or determined to be CBI, will continue for the duration of the contract without further notice, including during any contract extensions.

Authority: 7 U.S.C. 136 *et seq.;* 15 U.S.C. 2601 *et seq.;* and 21 U.S.C. 301 *et seq.*

Dated: December 19, 2022.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Program Support.

[FR Doc. 2022–28046 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2021–0743; FRL–10537–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Reporting in the FIFRA Grant Database (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted the following information collection request (ICR), Reporting in the FIFRA Grant Database (EPA ICR Number 2511.03, OMB Control Number 2070–0198) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). This is a proposed extension of the ICR, which is currently approved through December 31, 2022. Public comments were previously requested via the **Federal Register** on March 28, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments. The ICR, which is summarized in this document, describes the collection activities and estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before January 26, 2023.

ADDRESSES: *For submissions to EPA:* Submit your comments, referencing Docket ID No. EPA–HQ–OPP–2021–0743, using *https://www.regulations.gov.* For additional delivery options and information about EPA's dockets visit *https://www.epa.gov/dockets.* EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

For submissions to OMB: Submit comments and recommendations using *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Regulatory Support Branch (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1205; email address: *siu.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents that explain in detail the information EPA will be collecting are available in the docket for this ICR. The docket can be viewed online at *https://www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. Additional information about visiting EPA's dockets is available at *https://www.epa.gov/dockets.*

Abstract: This ICR describes the burden activities for the electronic collection of information for the pre-award burden activity for creating a work plan and the post-award and after-the-grant award activities related to reporting accomplishments to implement EPA's Federal Insecticide Fungicide and Rodenticide Act (FIFRA) State and Tribal Assistance Grant (STAG) program (7 U.S.C. 136u).

In 2019, a workgroup comprised of EPA, state, and tribal representatives converted the FIFRA Work Plan and Report Template (FIFRA Template), which was in Excel, into a pilot program of a web-based system housed in the Central Data Exchange (CDX) platform, called the FIFRA Grant Database (FGD). When the permanent use of the pilot program is approved by OMB, then the use of the FGD will become mandatory, replacing the excel web-based system entirely.

This ICR augments the ICR entitled ''EPA's General Regulation for Assistance Programs ICR'' (OMB Control No. 2030–0020; EPA ICR No. 0938.18) which accounts for the current PRA burden for the minimum management requirements for all recipients of EPA grants or cooperative agreements (assistance agreements).

This ICR provides the burden assessment for the FIFRA program specific activities associated with using a standardized online template for only the STAG program reporting.

Form Numbers: EPA Form 5700–33H.

Respondents/affected entities: State, local governments, Indian tribes, and U.S. territories that are grantees of Federal funds participating in the FIFRA STAG program.

Respondent's obligation to respond: Mandatory, as per 40 CFR parts 30 and 31.

Estimated number of respondents: 81 (total).

Frequency of response: Biannually (mid-year and end of year reporting).

Total estimated responses: 162 (per year).

Total estimated burden: 26,195 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated costs: $2,102,179 (per year), which includes an estimated cost of $0 for capital investment or maintenance and operational costs.

Changes in the estimates: There is no change in total estimated burden compared with the ICR currently approved by OMB.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–28058 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2021–0749; FRL–10539–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Foreign Purchaser Acknowledgement Statement of Unregistered Pesticides (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Foreign Purchaser Acknowledgement Statement of Unregistered Pesticides (EPA ICR Number 0161.16, OMB Control Number 2070–0027) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2022. Public comments were previously requested via the **Federal Register** on March 1, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments. The ICR, which is summarized in this notice, provides the Agency's estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before January 26, 2023.

ADDRESSES: *For submissions to EPA:* Submit your comments, referencing Docket identification (ID) No. EPA–HQ–OPPT–2021–0728, using *https://www.regulations.gov.* For additional delivery options and information about EPA's dockets, visit *https://www.epa.gov/dockets.* EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

For submissions to OMB: Submit comments within 30 days of publication of this notice using *https://www.reginfo.gov/public/do/PRAMain.* Find this particular ICR by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Regulatory Support Branch (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1205; email address: *siu.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the docket for this ICR. The docket can be viewed online at *https://www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's dockets, visit *https://www.epa.gov/dockets.*

Abstract: This ICR addresses the information collection activities associated with the mandate in section 17(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which requires an exporter of any pesticide not registered under FIFRA section 3 or sold under FIFRA section 6(a)(1) to obtain a signed statement from the foreign purchaser acknowledging that the purchaser is aware that the pesticide is not registered for use in, and cannot be sold in, the United States. A copy of this statement, which is known as the Foreign Purchaser Acknowledgement Statement, or FPAS, must be transmitted by EPA to the Designated National Authority or appropriate official of the government in the importing country. This information is submitted to EPA via mail or electronically through the Central Data Exchange (CDX) in the form of annual or per-shipment statements. EPA maintains original records and transmits copies, along with an explanatory letter, via email to appropriate government officials of the countries that are importing the pesticide.

In addition to the export notification for unregistered pesticides, FIFRA requires that all exported pesticides include appropriate labeling. There are different requirements for registered and unregistered products. The export labeling requirements meet the definition of third-party notification. This ICR includes burden estimates for the FPAS requirement for unregistered pesticides, as well as the labeling requirement for all exported pesticides, both registered and unregistered. The burden estimates for export labeling requirements have been consolidated in this ICR since the implementation of the 1993 pesticide export policy governing the export of pesticides, devices, and active ingredients used in producing pesticides, codified in 40 CFR part 168, subpart D.

Form Numbers: EPA Form 9600–026.

Respondents/affected entities: Entities potentially affected by this ICR are individuals or entities that either manufacture and export pesticides or that reformulate or repackage and export pesticides. The North American Industrial Classification System (NAICS) code assigned to the parties responding to this information is 3250A1.

Respondent's obligation to respond: Mandatory under FIFRA section 17(a)(2) and 40 CFR part 168, subpart D.

Estimated number of respondents: 2,240 (total).

Frequency of response: On occasion.

Total estimated burden: 16,660 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,265,501 (per year), includes $0 annualized capital or operation and maintenance costs.

Changes in the estimates: There is no change in burden from that currently approved by OMB. There were adjustments to the Agency burden estimate related to the ongoing COVID–19 public health emergency, during which time EPA had limited access to mail delivered by the postal service since March 2020. This scenario prompted EPA to announce a temporary COVID–19 flexibility to allow for secure electronic submissions (86 FR 46246, August 18, 2021) (FRL–8721–01–OCSPP). Given this circumstance, EPA cannot yet estimate the annual changes in the number of submissions over the last 3 years. Instead, this ICR relies on previous estimates and assumes the

numbers have largely remained the same over the past 3 years.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–28051 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0017; FRL–10540–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Petroleum Refineries: Catalytic Cracking Units, Catalytic Reforming Units, and Sulfur Recovery Units (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Petroleum Refineries: Catalytic Cracking Units, Catalytic Reforming Units, and Sulfur Recovery Units (EPA ICR Number 1844.12, OMB Control Number 2060–0554), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 31, 2023. Public comments were previously requested, via the **Federal Register**, on July 22, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before January 26, 2023.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2022–0017, to: (1) EPA online using *https://www.regulations.gov/* (our preferred method), or by email to *docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB's Office of Information and Regulatory Affairs using the interface at: *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

The EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov,* or in person, at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Petroleum Refineries: Catalytic Cracking Units, Catalytic Reforming Units, and Sulfur Recovery Units (40 CFR part 63, subpart UUU) apply to three types of affected units at either new and existing major source petroleum refineries: fluid catalytic cracking units (FCCU) for catalyst regeneration; catalytic reforming units (CRU); and sulfur recovery units (SRU). The rule also includes requirements for by-pass lines associated with the three affected units. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to the NESHAP.

Form Numbers: None.

Respondents/affected entities: Owners and operators of petroleum refineries that operate catalytic cracking units; catalytic reforming units; and sulfur recovery units.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart UUU).

Estimated number of respondents: 130 (total).

Frequency of response: Semiannually.

Total estimated burden: 16,100 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $10,000,000 (per year), which includes $8,020,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the estimates: The decrease in burden from the most-recently approved ICR is due to an adjustment. The adjustment decrease in burden is due to a decrease in the number of sources. Petroleum refinery capacities have been declining since 2020 and this ICR reflects updated respondent counts based on data collected by the U.S. Energy Information Administration. In addition, the burden for one-time activities following implementation of the 2015 final rule in the currently approved ICR were removed. This ICR reflects the on-going burden and costs for the existing facilities. Due to a decrease in the number of respondents, there has been a decrease in the capital/startup and/or operation and maintenance (O&M) costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–28074 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0119; FRL –10538–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Motor Vehicle and Engine Compliance Program Fees (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), Motor Vehicle and Engine Compliance Program Fees (EPA ICR Number 2080.08, OMB Control Number 2060–0545) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is proposed extension of the ICR, which is currently

approved through December 31, 2022. Public comments were previously requested via the **Federal Register** on April 8, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before January 26, 2023.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OAR–2013–0119, online using *www.regulations.gov* (our preferred method), by email to *a-and-r-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

For submissions to OMB: Submit comments and recommendations using *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Lynn Sohacki, Compliance Division, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood Dr., Ann Arbor, MI 48105; telephone number: 734–214–4851, fax number: 734–214–4869; email address: *sohacki.lynn@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: As required by the Clean Air Act, EPA has regulations establishing emission standards and other requirements for various classes of vehicles, engines, and evaporative emission components. These regulations require a manufacturer to demonstrate compliance prior to EPA granting it a ''Certificate of Conformity.'' EPA charges fees for administering this certification program. In 2004 and subsequently in 2008 the fees program was expanded to include nonroad categories of vehicles and engines, such as several categories of marine engines, locomotives, non-road recreational vehicles, many nonroad compression-ignition and spark-ignition engines and evaporative emission components. Manufacturers and importers of covered vehicles, engines and components are required to pay the applicable certification fees prior to their certification applications being reviewed by the Agency. Under section 208 of the Clean Air Act (42 U.S.C. 7542(c)) all information, other than trade secret processes or methods, must be publicly available. Information about fee payments is treated as confidential information prior to certification.

Form Numbers: 3520–29.

Respondents/affected entities: Manufacturers or importers of passenger cars, motorcycles, light trucks, heavy-duty truck engines, nonroad vehicles or engines, and evaporative emission components are required to receive a certificate of conformity from EPA prior to selling or introducing these products into commerce in the U.S.

Respondent's obligation to respond: Required to obtain or retain a benefit (40 CFR part 1027).

Estimated number of respondents: 579 (total).

Frequency of response: An average of approximately nine responses per respondent per year.

Total estimated burden: 1022 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $77,444 (per year), includes $12,364 annualized capital or operation and maintenance costs.

Changes in the estimates: There is a slight increase of three hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This slight increase is due to the variability in the number of certificates and, therefore, the number of fees paid from year to year. The estimate of the costs associated with the fees program have increased from $67,445 to $77,444 due to wage estimate increases.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–28057 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10515–01–OA]

Notification of Request for Nominations to the National Environmental Justice Advisory Council

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for nominations to the National Environmental Justice Advisory Council (NEJAC).

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations from a diverse range of qualified candidates to be considered for appointment to its National Environmental Justice Advisory Council (NEJAC). The NEJAC was chartered to provide advice regarding broad, cross-cutting issues related to environmental justice. This notice solicits nominations to fill approximately ten (10) new vacancies for terms through September 2024. To maintain the representation outlined by the charter, nominees will be selected to represent: academia, business and industry; community-based; non-governmental organizations; state and local governments; and tribal governments and indigenous organizations. We are interested in adding members located in in all EPA regions. Vacancies are anticipated to be filled by September 2023. Sources in addition to this **Federal Register** Notice will be utilized in the solicitation of nominees.

DATES: Nominations should be submitted in time to arrive no later than Friday, March 17, 2023.

ADDRESSES: Submit nominations electronically with the subject line NEJAC Membership 2023 to *nejac@epa.gov.* The Office of Environmental Justice and External Civil Rights will acknowledge receipt of nominations.

FOR FURTHER INFORMATION CONTACT: Paula Flores Gregg, NEJAC Designated Federal Officer, U.S. EPA; email: *nejac@epa.gov;* telephone: (214) 665–8123.

SUPPLEMENTARY INFORMATION: The NEJAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), Public Law 92–463. EPA established the NEJAC in 1993 to provide independent consensus advice to the EPA Administrator about a broad range of environmental issues related to environmental justice. The NEJAC conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. In accordance with Executive Order 14035, EPA values and

welcomes opportunities to increase diversity, equity, inclusion, and accessibility on its Federal advisory committees. EPA's Federal advisory committees have a workforce that reflects the diversity of the American people.

The Council consists of 32 members (including two Co-Chairpersons and two Vice-Chairpersons) appointed by EPA's Administrator. Members serve as non-Federal stakeholders who represent academia, business and industry; community-based organizations; non-governmental/environmental organizations; state and local governments; tribal governments and indigenous organizations, of which one member serves as a liaison to the National Tribal Caucus. Members are appointed for one (1); two (2) or three (3)-year terms with the possibility of reappointment for another term.

The NEJAC usually convenes 4 to 6 times a year, generally meeting face-to-face twice (2) a year in the Spring and the Fall and virtually for the remaining meetings. Additionally, members will be asked to participate in work groups to develop recommendations, advice letters, and reports to address specific policy issues. The average workload for members is approximately 20 to 25 hours per month, not including public meeting hours and with the expectation that the member will take part in two (2) or more workgroup activities. EPA provides reimbursement for travel and other incidental expenses associated with official Government business.

Nominations: Any interested person and/or organization may nominate qualified individuals for membership. Individuals are encouraged to self-nominate. The EPA values and welcomes opportunities to increase diversity, equity, inclusion and accessibility on its Federal advisory committees and is seeking to obtain nominations from all geographic locations of the United States of America. All nominations will be fully considered, but applicants need to be aware of the specific representation sought as outlined in the summary above. In addition, EPA is seeking nominees with knowledge in youth led or youth focused environmental organization; environmental measures; public health/health disparities; water infrastructure and other water concerns; farmworkers and pesticides; community sustainability and resiliency; green jobs and green infrastructure; land use and equitable development; and emerging inclusion of sub-populations such as the unhoused individuals, veterans, individuals in the criminal justice system, etc. Other criteria used to evaluate nominees will include:

- the background and experience that would help members contribute to the diversity of perspectives on the committee (*e.g.,* geographic, economic, social, cultural, educational background, professional affiliations, and other considerations),
- demonstrated experience with environmental justice and community sustainability issues at the national, state, or local level,
- excellent interpersonal and consensus-building skills,
- ability to volunteer time to attend meetings 4–6 times a year, participate in virtual and in-person meetings, volunteer time to take part in two (2) or more workgroup activities, attend listening sessions with the Administrator or other senior-level officials, develop policy recommendations to the Administrator, and prepare reports and advice letters, and
- willingness to commit time to the committee and demonstrated ability to work constructively and effectively on committees. The average workload for members is approximately 20 to 25 hours per month, not including public meeting hours and with the expectation that the member will take part in two (2) or more workgroup activities.

How to Submit Nominations: Any interested person or organization may nominate qualified persons to be considered for appointment to this advisory committee. Individuals are encouraged to self-nominate. Nominations will be submitted in electronic format following the template available at *https://www.epa.gov/environmentaljustice/nominations-nejac.* To be considered, all nominations should include:

- Current contact information for the nominee/applicant, including the nominee's/applicant's name, organization (and position within that organization), current business address, email address, telephone numbers and the stakeholder category position you are interested in.
- Brief Statement describing the nominee's/applicant's interest in serving on the NEJAC.
- Résumé and a short biography describing the professional and educational qualifications of the nominee, including a list of relevant activities, and any current or previous service on advisory committees.
- Brief statements describing experience as it relates to engaging affected communities, understanding environmental justice/relevant issues, consensus building, communication skills and availability.
- Letter[s] of recommendation from a third party supporting the nomination. Letter[s] should describe how the nominee's experience and knowledge will bring value to the work of the NEJAC.

Dated: December 20, 2022.

Matthew Tejada,

Deputy Assistant Administrator for Office of Environmental Justice and External Civil Rights.

[FR Doc. 2022–28078 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0024; FRL–10518–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Commercial and Industrial Solid Waste Incineration (CISWI) Units (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Commercial and Industrial Solid Waste Incineration (CISWI) Units (EPA ICR Number 1926.09, OMB Control Number 2060–0450), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 31, 2023. Public comments were previously requested, via the **Federal Register**, on July 22, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before January 26, 2023.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2022–0024, to: (1) EPA online using *https://www.regulations.gov/* (our preferred method), or by email to *docket@epa.gov,* or by mail to: EPA Docket Center, Environmental

Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460; and (2) OMB's Office of Information and Regulatory Affairs using the interface at: *https://www.reginfo.gov/public/do/PRAMain.* Find this specific information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

The EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at either *https://www.regulations.gov,* or in person, at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The New Source Performance Standards (NSPS) for the regulations published at 40 CFR part 60, subpart CCCC apply to either owners or operators of a combustion device used to combust commercial and industrial waste, and that meet either of the following two criteria: (1) began construction either on or after December 31, 1999; or (2) began either reconstruction or modification either on or after June 1, 2001. Commercial and industrial waste is a solid waste combusted in an enclosed device using controlled-flame combustion without energy recovery, which is a distinct operating unit of any commercial or industrial facility, including field-erected, modular, and custom-built incineration units operating with starved or excess air, or solid waste combusted in an air curtain incinerator without energy recovery that is a distinct operating unit of any commercial or industrial facility. In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to the NSPS.

Form Numbers: None.

Respondents/affected entities: Owners and operators of CISWI units that are subject to the year 2000 standards.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart CCCC).

Estimated number of respondents: 13 (total).

Frequency of response: Annually, semiannually.

Total estimated burden: 2,800 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $512,000 (per year), which includes $176,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment decrease in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This decrease in burden is not due to any program changes. Instead, the decrease is due to a decrease in the number of respondents to reflect facility closures. There is also a decrease in Capital/Startup and Operation and Maintenance costs due to a decrease in the number of sources.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–28065 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0733; FRL–9948–02–OCSPP]

Carbon Tetrachloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final revision to the risk determination for the carbon tetrachloride risk evaluation issued under the Toxic Substances Control Act (TSCA). The revision to the carbon tetrachloride risk determination reflects the announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. EPA determined that carbon tetrachloride, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use. In addition, this revised risk determination does not reflect an assumption that workers always appropriately wear personal protective equipment (PPE). EPA understands that there could be adequate occupational safety protections in place at certain workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being ''outdated and inadequate for ensuring protection of worker health,'' or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. This revision supersedes the condition of use-specific no unreasonable risk determinations in the November 2020 Carbon Tetrachloride Risk Evaluation and withdraws the associated TSCA order included in the November 2020 Carbon Tetrachloride Risk Evaluation.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0733, is available online at *https://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Claudia Menasche, Office of Pollution Prevention and Toxics (7404M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–3391; email address: *Menasche.Claudia@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process (including recycling), distribute in commerce, use or dispose of carbon tetrachloride. Since other entities may also be interested in this revision to the risk determination, EPA has not attempted to describe all the specific entities that may be affected by this action.

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

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence, and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n* v. *State Farm Mutual Auto. Ins. Co.,* 463 U.S. 29, 42 (1983). Pursuant to such authority, EPA has reconsidered and is now finalizing a revised risk determination for CTC.

C. What action is EPA taking?

EPA is announcing the availability of the final revision to the risk determination for the carbon tetrachloride risk evaluation issued under TSCA that published in November 2020 (Ref. 1). In August 2022, EPA sought public comment on the draft revisions (87 FR 52766, August 29, 2022). EPA appreciates the public comments received on the draft revision to the carbon tetrachloride risk determination. After review of these comments and consideration of the specific circumstances of carbon tetrachloride, EPA concludes that the Agency's risk determination for carbon tetrachloride is better characterized as a whole chemical risk determination rather than condition-of-use-specific risk determinations. Accordingly, EPA is revising and replacing Section 5 of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2) where the findings of unreasonable risk to health were previously made for the individual conditions of use evaluated. EPA is also withdrawing the previously issued TSCA section 6(i)(l) order for two conditions of use previously determined not to present unreasonable risk which was included in Section 5.4.1 of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2).

This final revision to the carbon tetrachloride risk determination is consistent with EPA's plans to revise specific aspects of the first ten TSCA chemical risk evaluations to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. As a result of this revision, removing the assumption that workers always and appropriately wear PPE (see Unit II.C.) would not alter the conditions of use that drive the unreasonable risk determination for carbon tetrachloride. However, without the assumed use of PPE, inhalation exposures to workers now also drive the unreasonable risk and, in addition to there being risks of cancer effects from dermal exposures, risks of non-cancer effects (specifically liver toxicity) from dermal exposures are now also driving the unreasonable risk. In addition, the November 2020 Carbon Tetrachloride Risk Evaluation contained a typographical error in the acute dermal point of departure (POD). This error was corrected in a memorandum made available to the public in the docket July 2022 and the changes to the risk estimates for acute dermal exposures are reflected in the revision to the risk determination (Ref. 14). The corrections do not alter the conditions of use that drive the unreasonable risk determination for carbon tetrachloride. EPA is not making condition-of-use-specific risk determinations for those conditions of use, and for purposes of TSCA section 6(i), EPA is not issuing a final order under TSCA section 6(i)(1) for the conditions of use that do not drive the unreasonable risk and does not consider the revised risk determination to constitute a final agency action at this point in time. Overall, 13 conditions of use out of 15 EPA evaluated drive the carbon tetrachloride whole chemical unreasonable risk determination due to risks identified for human health. *The full list of the conditions of use evaluated for the* carbon tetrachloride *TSCA risk evaluation is in Table 1–4 of the November* 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2).

II. Background

A. Why is EPA re-issuing the risk determination for the carbon tetrachloride risk evaluation conducted under TSCA?

In accordance with Executive Order 13990 (''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis'') and other Administration priorities (Refs. 3, 4, 5, and 6), EPA reviewed the risk evaluations for the first ten chemical substances, including carbon tetrachloride, to ensure that they meet the requirements of TSCA, including conducting decision-making in a manner that is consistent with the best available science.

As a result of this review, EPA announced plans to revise specific aspects of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help ensure the protection of human health and the environment (Ref. 7). Following a review of specific aspects of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2) and after considering comments received on a draft revised risk determination for carbon tetrachloride, EPA has determined that making an unreasonable risk determination for carbon tetrachloride as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation, is the most appropriate approach for carbon tetrachloride under the statute and implementing regulations. In addition, EPA's final risk determination is explicit insofar as it does not rely on assumptions regarding the use of PPE in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce worker exposures; rather, the use of PPE as a means of addressing unreasonable risk will be considered during risk management, as appropriate.

Separately, EPA is conducting a screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including this chemical. For carbon tetrachloride the exposure pathways that were or could be regulated under another EPA administered statute were excluded from the final risk evaluation (see section 1.4.3 of the November 2020 Carbon Tetrachloride Risk Evaluation). This resulted in the ambient air and ambient/drinking water pathways for carbon tetrachloride not being assessed. The goal of the recently-developed screening approach is to remedy this exclusion and to determine if there may be risks that were unaccounted for in the carbon tetrachloride risk evaluation.

The screening-level approach has gone through public comment and independent external peer review through the SACC. The Agency received the final peer review report on May 18, 2022, and has reviewed public comments and SACC comments. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for carbon tetrachloride.

This action pertains only to the risk determination for carbon tetrachloride. While EPA intends to consider and may take additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing these risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities in accordance with statutory deadlines.

B. What is a whole chemical view of the unreasonable risk determination for the carbon tetrachloride risk evaluation?

TSCA section 6 repeatedly refers to determining whether a chemical *substance* presents unreasonable risk under its conditions of use. Stakeholders have disagreed over whether a chemical substance should receive: A single determination that is comprehensive for the chemical substance after considering the conditions of use, referred to as a whole-chemical determination; or multiple determinations, each of which is specific to a condition of use, referred to as condition-of-use-specific determinations.

As explained in the **Federal Register** document announcing the availability of the draft revised risk determination for carbon tetrachloride (87 FR 52766, August 29, 2022 (FRL–9948–01–OCSPP)), the proposed Risk Evaluation Procedural Rule (Ref. 8) was premised on the whole chemical approach to making unreasonable risk determinations. In that proposed rule, EPA acknowledged a lack of specificity in statutory text that might lead to different views about whether the statute compelled EPA's risk evaluations to address all conditions of use of a chemical substance or whether EPA had discretion to evaluate some subset of conditions of use (*i.e.,* to scope out some manufacturing, processing, distribution in commerce, use, or disposal activities), but also stated that ''EPA believes the word 'the' [in TSCA section 6(b)(4)(A)] is best interpreted as calling for evaluation that considers all conditions of use.'' The proposed rule, however, was unambiguous on the point that unreasonable risk determinations would be for the chemical substance as a whole, even if based on a subset of uses. See Ref. 8 at pages 7565–66 (''TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether 'a chemical substance' presents an unreasonable risk of injury to health or the environment 'under the conditions of use.' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on 'the conditions of use.' In this context, EPA believes the word 'the' is best interpreted as calling for evaluation that considers all conditions of use.''). In the proposed regulatory text, EPA proposed to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. (Ref. 8 at 7480.)

The final Risk Evaluation Procedural Rule stated (82 FR 33726, July 20, 2017 (FRL–9964–38)) (Ref. 9): ''As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents'' (40 CFR 702.47). For the unreasonable risk determinations in the first ten risk evaluations, EPA applied this provision by making individual risk determinations for each condition of use evaluated as part of each risk evaluation document (*i.e.,* the condition-of-use-specific approach to risk determinations). That approach was based on one particular passage in the preamble to the final Risk Evaluation Rule which stated that EPA will make individual risk determinations for all conditions of use identified in the scope. (Ref. 9 at 33744).

In contrast to this portion of the preamble of the final Risk Evaluation Rule, the regulatory text itself and other statements in the preamble reference a risk determination *for the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted previously from 40 CFR 702.47, the text explains that ''[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an

unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents'' (Ref. 9, emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). See, for example, 40 CFR 702.41(a)(6), which explains that the extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk. Notwithstanding the one preambular statement about condition-of-use-specific risk determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA's part, and ''as EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk'' (Ref. 9 at 33729).

Therefore, notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation. A panel of the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point. *Safer Chemicals* v. *EPA,* 943 F.3d. 397, 413 (9th Cir. 2019) (holding a challenge about ''use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear'').

EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. The Agency expects that this case-by-case approach will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

With regard to the specific circumstances of carbon tetrachloride, EPA has determined that a whole chemical approach is appropriate for carbon tetrachloride in order to protect health. The whole chemical approach is appropriate for carbon tetrachloride because there are benchmark exceedances for a substantial number of conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, and disposal) for workers and occupational non-users and risk of severe health effects (specifically cancer and liver toxicity) associated with carbon tetrachloride exposures. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of the conditions of use drive the unreasonable risk; therefore, it is appropriate for the Agency to make a determination for carbon tetrachloride that the whole chemical presents an unreasonable risk.

As explained later in this document, the revisions to the unreasonable risk determination (Section 5 of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2)) follow the issuance of a draft revision to the TSCA carbon tetrachloride unreasonable risk determination (87 FR 52766, August 29, 2022) and the receipt of public comment. A response to comments document is also being issued with the final revised unreasonable risk determination for carbon tetrachloride (Ref. 10). The revisions to the unreasonable risk determination are based on the existing risk characterization section of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2) (Section 4) and do not involve additional technical or scientific analysis. The discussion of the issues in this **Federal Register** document and in the accompanying final revised risk determination for carbon tetrachloride supersede any conflicting statements in the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2) and the earlier response to comments document (Ref. 11). EPA views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

For purposes of TSCA section 6(i), EPA is making a risk determination on carbon tetrachloride as a whole chemical. Under the revised approach, the ''whole chemical'' risk determination for carbon tetrachloride supersedes the no unreasonable risk determinations for carbon tetrachloride that were premised on a condition-of-use-specific approach to determining unreasonable risk and also contains an order withdrawing the TSCA section 6(i)(1) order in Section 5.4.1 of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2).

C. What revision is EPA now making final about the use of PPE for the carbon tetrachloride risk evaluation?

In the risk evaluations for the first ten chemical substances, as part of the unreasonable risk determination, EPA assumed for several conditions of use that workers were provided and always used PPE in a manner that achieves the stated assigned protection factor (APF) for respiratory protection, or used impervious gloves for dermal protection. In support of this assumption, EPA used reasonably available information such as public comments indicating that some employers, particularly in the industrial setting, provide PPE to their employees and follow established worker protection standards (*e.g.,* OSHA requirements for protection of workers).

For the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2), EPA assumed, based on reasonably available information that workers use PPE—specifically, respirators with an APF ranging from 10 to 50—for 12 conditions of use and gloves with a PF of 20 for 13 conditions of use. In the November 2020 Carbon Tetrachloride Risk Evaluation, EPA determined that there is unreasonable risk to these workers even with this assumed PPE use.

EPA is revising the assumption for carbon tetrachloride that workers always and properly use PPE. However, this does not mean that EPA questions the veracity of public comments which describe occupational safety practices often followed by industry. EPA believes it is appropriate when conducting risk evaluations under TSCA to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations of workers who may not

be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

In addition, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements (*e.g.,* chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. Consistent with this approach, the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2) characterized risk to workers both with and without the use of PPE. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified, or to ensure that applicable OSHA requirements or industry or sector best practices that address the unreasonable risk are required for all potentially exposed and susceptible subpopulations (including self-employed individuals and public sector workers who are not covered by an OSHA State Plan).

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, however, EPA does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice related to PPE use is consistently and always properly applied. Mitigation scenarios included in the EPA risk evaluation (*e.g.,* scenarios considering use of various PPE) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities have adopted these practices for the purposes of making the TSCA risk determination (Ref. 12).

Therefore, EPA is making a determination of unreasonable risk for carbon tetrachloride from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being ''outdated and inadequate for ensuring protection of worker health,'' (Ref. 13), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

In accordance with this approach, EPA is finalizing the revision to the carbon tetrachloride risk determination without relying on assumptions regarding the occupational use of PPE in making the unreasonable risk determination under TSCA section 6; rather, information on the use of PPE as a means of mitigating risk (including public comments received from industry respondents about occupational safety practices in use) will be considered during the risk management phase, as appropriate. This represents a change from the approach taken in the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2). As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls, to the extent that applying those measures would address the identified unreasonable risk, including unreasonable risk to potentially exposed or susceptible subpopulations. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

Removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for carbon tetrachloride does not result in additional conditions of use to the original 13 conditions of use that drive the unreasonable risk for carbon tetrachloride as a whole chemical. However, the impact of removing the assumption of PPE use causes inhalation exposures to workers to also drive the unreasonable risk and, in addition to there being risks of cancer effects from dermal exposures, risks of non-cancer effects (specifically liver toxicity, including risk associated with acute dermal exposures identified after the July 2022 corrections to the risk estimates (Ref. 14)) from dermal exposures are now also driving the unreasonable risk. The finalized revision to the carbon tetrachloride risk determination clarifies that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance; rather, the use of PPE as a means of addressing unreasonable risk will be considered during risk management as appropriate.

D. What is carbon tetrachloride?

Carbon tetrachloride is a high production volume solvent. Currently, the vast majority of carbon tetrachloride is used as a feedstock in the production of hydrochlorofluorocarbons (HCFCs), hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs). EPA has identified information on the regulated use of carbon tetrachloride as a process agent in the manufacturing of petrochemicals-derived and agricultural products and other chlorinated compounds such as chlorinated paraffins, chlorinated rubber and others that may be used downstream in the formulation of solvents, adhesives, asphalt, paints and coatings, and elimination of nitrogen trichloride in the production of chlorine and caustic soda. The use of carbon tetrachloride for non-feedstock uses (*i.e.,* process agent, laboratory chemical) is regulated in accordance with the Montreal Protocol.

E. What conclusions is EPA finalizing today in the revised TSCA risk evaluation based on the whole chemical approach and not assuming the use of PPE?

EPA determined that carbon tetrachloride presents an unreasonable risk to health under the conditions of use. EPA's unreasonable risk

determination for carbon tetrachloride as a chemical substance is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing (Domestic Manufacture);
- Manufacturing (Import);
- Processing as a reactant in the production of hydrochlorofluorocarbon, hydrofluorocarbon, hydrofluoroolefin, and perchloroethylene;
- Processing: Incorporation into formulation, mixtures or reaction products (petrochemicals-derived manufacturing; agricultural products manufacturing; other basic organic and inorganic chemical manufacturing);
- Processing: Repackaging for use as a laboratory chemical;
- Processing: Recycling;
- Industrial/commercial use as an industrial processing aid in the manufacture of petrochemicals-derived products and agricultural products;
- Industrial/commercial use in the manufacture of other basic chemicals (including chlorinated compounds used in solvents, adhesives, asphalt, paints and coatings, and elimination of nitrogen trichloride in the production of chlorine and caustic soda);
- Industrial/commercial use in metal recovery;
- Industrial/commercial use as an additive;
- Industrial/commercial use in specialty uses by the Department of Defense;
- Industrial/commercial use as a laboratory chemical; and
- Disposal.

EPA notes that the names of some of these conditions of use have been slightly modified from the draft revised risk determination for clarity and consistency with Table 1–4 of the November 2020 Carbon Tetrachloride Risk Evaluation. The following conditions of use do not drive EPA's unreasonable risk determination for carbon tetrachloride:

- Processing as a reactant/intermediate in reactive ion etching; and
- Distribution in commerce.

EPA is not making condition of use-specific risk determinations for these conditions of use, is not issuing a final order under TSCA section 6(i)(1) for these conditions of use and does not consider the revised risk determination for carbon tetrachloride to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose a risk management regulatory action to the extent necessary so that carbon tetrachloride no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (*e.g.,* processing, distribution in commerce) to address downstream activities (*e.g.,* commercial uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.

III. Summary of Public Comments

EPA received a total of 12 public comments on the August 29, 2022, draft revised risk determination for carbon tetrachloride during the comment period that ended September 28, 2022. Commenters included trade organizations, industry stakeholders, environmental groups, and non-governmental health advocacy organizations. A separate document that summarizes all comments submitted and EPA's responses to those comments has been prepared and is available in the docket for this notice (Ref. 10).

IV. Revision of the November 2020 Carbon Tetrachloride Risk Evaluation

A. Why is EPA revising the risk determination for the carbon tetrachloride risk evaluation?

EPA is finalizing the revised risk determination for the carbon tetrachloride risk evaluation pursuant to TSCA section 6(b) and consistent with Executive Order 13990, (''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis'') and other Administration priorities (Refs. 3, 4, 5, and 6). EPA is revising specific aspects of the first ten TSCA existing chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. For the carbon tetrachloride risk evaluation, this includes: (1) Making the risk determination in this instance based on the whole chemical substance instead of by individual conditions of use and (2) Emphasizing that EPA does not rely on the assumed use of PPE when making the risk determination.

B. What are the revisions?

EPA is now finalizing the revised risk determination for the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2) pursuant to TSCA section 6(b). Under the revised determination (Ref. 1), EPA concludes that carbon tetrachloride, as evaluated in the risk evaluation as a whole, presents an unreasonable risk of injury to health when evaluated under its conditions of use. This revision replaces the previous unreasonable risk determinations made for carbon tetrachloride by individual conditions of use, supersedes the determinations (and withdraws the associated order) of no unreasonable risk for the conditions of use identified in the TSCA section 6(i)(1) no unreasonable risk order, and clarifies the lack of reliance on assumed use of PPE as part of the risk determination.

These revisions do not alter any of the underlying technical or scientific information that informs the risk characterization, and as such the hazard, exposure, and risk characterization sections are not changed. The revision to the unreasonable risk determination considers the corrections to the risk estimates for acute dermal exposures placed in the docket for the carbon tetrachloride risk evaluation in July 2022; that memorandum corrected a typographical error in the acute dermal point of departure (POD) and the risk estimates based on that POD in the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 14). The discussion of the issues in this *Notice* and in the accompanying final revision to the risk determination supersede any conflicting statements in the prior executive summary from the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2) and the response to comments document (Ref. 11).

The revised unreasonable risk determination for carbon tetrachloride includes additional explanation of how the risk evaluation characterizes the applicable OSHA requirements, or industry or sector best practices, and also clarifies that no additional analysis was done, and the risk determination is based on the risk characterization (Section 4) of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2) and reflects the memorandum correcting risk estimates for acute dermal exposures (Ref. 14).

C. Will the revised risk determination be peer reviewed?

The risk determination (Section 5 of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2))

was not part of the scope of the Science Advisory Committee on Chemicals (SACC) peer review of the carbon tetrachloride risk evaluation. Thus, consistent with that approach, EPA did not conduct peer review of the final revised unreasonable risk determination for the carbon tetrachloride risk evaluation because no technical or scientific changes were made to the hazard or exposure assessments or the risk characterization.

V. Order Withdrawing Previous Order Regarding Unreasonable Risk Determinations for Certain Conditions of Use

EPA is also issuing a new order to withdraw the TSCA Section 6(i)(1) no unreasonable risk order issued in Section 5.4.1 of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2). This final revised risk determination supersedes the condition of use-specific no unreasonable risk determinations in the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2). The order contained in Section 5.5 of the revised risk determination (Ref. 1) withdraws the TSCA section 6(i)(1) order contained in Section 5.4.1 of the November 2020 Carbon Tetrachloride Risk Evaluation (Ref. 2). Consistent with the statutory requirements of section 6(a), the Agency will propose risk management action to address the unreasonable risk determined in the carbon tetrachloride risk evaluation.

VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Unreasonable Risk Determination for Carbon Tetrachloride. December 2022.
2. EPA. Risk Evaluation for Carbon Tetrachloride. November 2020. EPA Document No. EPA–740–R1–8014. *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0499-0047.*
3. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. **Federal Register** (86 FR 7037, January 25, 2021).
4. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. **Federal Register** (86 FR 7009, January 25, 2021).
5. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. **Federal Register** (86 FR 7619, February 1, 2021).
6. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. **Federal Register** (86 FR 8845, February 10, 2021).
7. EPA. Press Release; EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 2021. *https://www.epa.gov//epa-announces-path-forward-tsca-chemical-risk-evaluations.*
8. EPA. Proposed Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. **Federal Register** (82 FR 7562, January 19, 2017) (FRL–9957–75).
9. EPA. Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. **Federal Register** (82 FR 33726, 33744, July 20, 2017).
10. EPA. Response to Public Comments to the Revised Unreasonable Risk Determination; Carbon Tetrachloride. December 2022.
11. EPA. Summary of External Peer Review and Public Comments and Disposition for Carbon Tetrachloride. October 2020. Available at: *https://www.regulations.gov//HQ-OPPT-2019-0499-0062.*
12. Occupational Safety and Health Administration (OSHA). Top 10 Most Frequently Cited Standards for Fiscal Year 2021 (Oct. 1, 2020, to Sept. 30, 2021). Accessed October 13, 2022. *https://www.osha.gov/citedstandards.*
13. OSHA. Permissible Exposure Limits—Annotated Tables. Accessed June 13, 2022. *https://www.osha.gov/pels.*
14. EPA. Correction of Dermal Acute Hazard and Risk Values in the Final Risk Evaluation for Carbon Tetrachloride. Memorandum. July 27, 2022. Docket EPA–HQ–OPPT–2019–0499–0064. *https://www.regulations.gov//EPA-HQ-OPPT-2019-0499-0064.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 20, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–28041 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10487–01–OMS]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, Michigan Environment Great Lakes, & Energy (EGLE)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the Environmental Protection Agency's (EPA) approval of the Michigan Environment Great Lakes, & Energy (EGLE) request to revise/modify certain of its EPA-authorized programs to allow electronic reporting.

DATES: EPA approves the authorized program revisions/modifications as of December 27, 2022.

FOR FURTHER INFORMATION CONTACT: Shirley M. Miller, U.S. Environmental Protection Agency, Office of Information Management, Mail Stop 2824T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–2908, *miller.shirley@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On October 18,2022, the Michigan Environment Great Lakes, & Energy (EGLE) submitted an application titled MiEnviro Portal system for revisions/modifications to its EPA-approved programs under title 40 CFR to allow new electronic reporting. EPA reviewed EGLE's request to revise/modify its EPA-authorized programs and, based on

this review, EPA determined that the application met the standards for approval of authorized program revisions/modifications set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve EGLE's request to revise/modify its following EPA-authorized programs to allow electronic reporting under 40 CFR is being published in the **Federal Register**:

Part 52: Approval and Promulgation of Implementation Plans (SIP/Clean Air Act Title II) Reporting under CFR 50–52

Part 60: Standards of Performance for New Stationary Sources (NSPS/CAR/Clean Air Act Title III) Reporting under CFR 60 & 65

Part 62: Approval and Promulgation of State Plans for Designated Facilities and Pollutants (NSPS/Clean Air Act Title III—Hospital/Medical) Reporting under CFR 60 & 65

Part 63: National Emission Standards for Hazardous Air Pollutants for Source Categories (NESHAP MACT/Clean Air Act Title III) Reporting under CFR 61, 63 & 65

Part 70: State Operating Permit Programs (Clean Air Act Title V) Reporting under CFR 70

Part 123: EPA-Administered Permit Programs: the National Pollutant Discharge Elimination System (NPDES) Reporting under CFR 122 & 125

Part 233: ''404'' State Program Regulations (Ocean Dumping) Reporting under CFR 233

Part 403: General Pretreatment Regulations for Existing and New Sources of Pollution Reporting under CFR 403–471

Part 501: State Sludge Management Program Regulations Reporting under CFR 501 & 503

Part 239: Requirements for State Permit Program Determination of Adequacy (RCRA Subtitle C) Reporting under CFR 240–259

Part 271: Requirements for Authorization of State Hazardous Waste Programs (RCRA Subtitle C) Reporting under CFR 260–270, 272–279

Part 132: Great Lakes Water Quality Standards (WQS) Reporting under CFR 130–132

EGLE was notified of EPA's determination to approve its application with respect to the authorized programs listed above.

Dated: December 16, 2022.

Jennifer Campbell,

Director, Office of Information Management.

[FR Doc. 2022–28146 Filed 12–23–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1787]

Federal Reserve Bank Services

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) has approved the private-sector adjustment factor (PSAF) for 2023 of $23.7 million and the 2023 fee schedules for Federal Reserve priced services and electronic access. These actions were taken in accordance with the Monetary Control Act of 1980, which requires that, over the long run, fees for Federal Reserve priced services be established based on all direct and indirect costs, including the PSAF.

DATES: The new fee schedules become effective January 3, 2023.

FOR FURTHER INFORMATION CONTACT: For questions regarding the fee schedules: Ian Spear, Assistant Director, (202) 452–3959; Christian Miller, Lead Financial Institution Policy Analyst, (202) 452–3769; Division of Reserve Bank Operations and Payment Systems. For questions regarding the PSAF: Rebecca Royer, Deputy Associate Director, (202) 736–5662; Sarah Skariah, Senior Financial Institution Policy Analyst, (202) 973–6882, Division of Reserve Bank Operations and Payment Systems. For users of TTY–TRS, please call 711 from any telephone, anywhere in the United States. Copies of the 2023 fee schedules for the check services are available from the Board, the Federal Reserve Banks, or the Federal Reserve Financial Services website at *www.FRBservices.org.*

SUPPLEMENTARY INFORMATION:

I. Private-Sector Adjustment Factor, Priced Services Cost Recovery, and Overview of 2023 Price Changes

A. Overview—Each year, as required by the Monetary Control Act (MCA) of 1980, the Reserve Banks set fees for priced services provided to financial institutions. These fees are set to recover, over the long run, all direct and indirect costs and imputed costs, including financing costs, taxes, and certain other expenses, as well as the return on equity (profit) that would have been earned if a private-sector business provided the services.[1] The imputed costs and imputed profit are collectively referred to as the private-sector adjustment factor (PSAF).

From 2012 through 2021, the Reserve Banks recovered 103.0 percent of their total expenses (including imputed costs) and targeted after-tax profits or return on equity (ROE).[2] During that period, check services, the Fedwire® Funds Service, National Settlement Service, and Fedwire Securities Service achieved full cost recovery. FedACH® Services achieved 97.9 percent cost recovery as a result of the Reserve Banks' development and implementation of a multiyear technology initiative to modernize the FedACH Services processing platform capabilities. Although the modernized platform was implemented in 2021, the Reserve Banks are continuing to invest in platform capabilities, as well as resiliency initiatives, as part of a broader enhancement strategy. At the same time, the Reserve Banks have made limited changes to existing FedACH Services fees to provide price stability for customers in alignment with pricing policies.[3]

Table 1 summarizes 2021 actual, 2022 forecasted, and 2023 budgeted annual cost recovery rates for all priced services, excluding FedNow℠ Service cost and revenue.[4] Cost recovery is

[1] Although the Monetary Control Act does not define ''over the long run,'' the Board has generally measured long-run cost recovery for mature services to be over a 10-year rolling time frame. The Board currently views a 10-year cost recovery expectation as appropriate for assessing mature services, which are those that have achieved a critical mass of customer participation and generally have stable and predictable volumes, costs, and revenues. The 10-year recovery rate is based on the pro forma income statements for Federal Reserve priced services published in the Board's *Annual Report.* In accordance with Accounting Standards Codification (ASC) 715 *Compensation—Retirement Benefits,* the Reserve Banks recognized a $686.5 million cumulative reduction in equity related to the priced services' benefit plans through 2021. Including this cumulative reduction in equity from 2012 to 2021 results in cost recovery of 94.3 percent for the 10-year period. This measure of long-run cost recovery is also published in the Board's *Annual Report.*

[2] The Board communicated in its 2019 Notice *Federal Reserve Actions to Support Interbank Settlement of Instant Payments* (''2019 Notice'') that it expects the FedNow Service to achieve its first instance of long run cost recovery outside the 10-year time frame typically applied to mature services. New services like the FedNow Service may not initially have stable volumes, costs, and revenues. Application of the 10-year rolling time frame used to evaluate mature services to the FedNow Service would result in prohibitively high or unnecessarily volatile pricing, negatively affecting the Federal Reserve's public policy objectives in providing the service. See ''Federal Reserve Actions to Support Interbank Settlement of Instant Payments,'' 84 FR 39297, (August 9, 2019). Available at: *https://www.govinfo.gov/content/pkg/FR-2019-08-09/pdf/2019-17027.pdf.*

[3] In alignment with the Board's *Principles for the Pricing of Federal Reserve Bank Services,* the Reserve Banks will continue to assess the tradeoffs between price stability for customers, investment in technology infrastructure to reflect desirable longer-run improvements in the ACH system, and the expectation of achieving full cost recovery for the FedACH Service over the long run. See Board of Governors of the Federal Reserve System, ''Adoption of Fee Schedules and Pricing Principles for Federal Reserve Bank Services,'' 46 FR 1338, 1343 (Jan. 6, 1981). *Available at https://cdn.loc.gov/service/ll/fedreg/fr046/fr046003/fr046003.pdf.*

[4] Per its 2019 Notice, the Board will disclose the FedNow Service's costs, inclusive of PSAF-related expenses, beginning the year the service is available to participating banks (currently anticipated in mid-

forecasted to be 101.1 percent in 2022 and budgeted to be 100.2 percent in 2023.

TABLE 1—AGGREGATE PRICED SERVICES PRO FORMA COST AND REVENUE PERFORMANCE [A]

[Dollars in millions]

Year	Revenue 1 [b]	Total expense 2 [c]	Net income (ROE) 3 [1 − 2]	Targeted ROE 4 [d]	Recovery rate after targeted ROE (%) 5 [e] [1/(2 + 4)]
2021 (actual)	456.0	452.7	3.3	4.4	99.8
2022 (forecast)	470.1	458.0	12.1	7.2	101.1
2023 (budget)	495.8	486.2	9.6	8.4	100.2

[a] Calculations in this table and subsequent pro forma cost and revenue tables may be affected by rounding. Excludes amounts related to the development of the FedNow Service.

[b] Revenue includes imputed income on investments when equity is imputed at a level that meets minimum capital requirements and, when combined with liabilities, exceeds total assets (attachment 1). For 2023, the projected revenue assumes implementation of the fee changes.

[c] The calculation of total expense includes operating, imputed, and other expenses. Imputed and other expenses include taxes, Board of Governors' priced services expenses, the cost of float, and interest on imputed debt, if any. Credits or debits related to the accounting for pension plans under ASC 715 are also included.

[d] Targeted ROE is the after-tax ROE included in the PSAF.

[e] The recovery rates in this and subsequent tables do not reflect the unamortized gains or losses that must be recognized in accordance with ASC 715. Future gains or losses, and their effect on cost recovery, cannot be projected.

Table 2 provides an overview of cost recovery budgets, forecasts, and performance for the 10-year period from 2012 to 2021, 2021 actual, 2022 budget, 2022 forecast, and 2023 budget by priced service.

TABLE 2—PRICED SERVICES COST RECOVERY

[Percent)]

Priced service	2012–2021	2021 Actual	2022 Budget [a]	2022 Forecast	2023 Budget [b]
All services	103.0	99.8	101.3	101.1	100.2
Check	109.1	103.2	97.1	100.4	100.1
FedACH	97.9	98.0	100.4	102.3	100.7
Fedwire Funds and NSS	102.1	98.6	100.3	99.2	97.7
Fedwire Securities	102.4	103.8	149.4	108.4	109.3

[a] The 2022 budget figures reflect the final budgets as approved by the director of the Division of Reserve Bank Operations and Payment Systems under delegated authority given by the Board, who conditionally approved the final budgets in December 2021. See Board of Governors of the Federal Reserve System, ''2022 Federal Reserve Bank Budget Memo and Addendum'' available at 2022 Federal Reserve Bank Budget Memo and Addendum. These budget figures incorporate the implementation of a new cost accounting framework and a new Enterprise Resource Planning application, which had not been fully implemented when the initial cost recovery figures for 2022 budget were calculated and reported in last year's **Federal Register** Notice.

[b] The 2023 budget figures reflect preliminary budget information from the Reserve Banks. The Reserve Banks will submit final budget data to the Board in November 2022, for Board consideration in December 2022.

1. *2022 Forecasted Performance*—The Reserve Banks forecast that they will recover 101.1 percent of the costs of providing priced services in 2022, including total expense and targeted ROE, compared with a 2022 budgeted recovery rate of 101.3 percent, as shown in table 2. Overall, the Reserve Banks forecast that they will fully recover actual and imputed costs and earn net income of $12.1 million, compared with the targeted ROE of $7.2 million. The Reserve Banks forecast that check services, the FedACH Services, and the Fedwire Securities Service will achieve full cost recovery.[5] The Reserve Banks forecast that the Fedwire Funds Service and the National Settlement Service will not achieve full cost recovery in 2022. Forecasted under-recovery in 2022 for the Fedwire Funds Service and the National Settlement Service is driven by an effort to avoid significant price volatility for customers while maintaining long-run cost recovery.

2. *2023 Private-Sector Adjustment Factor*—The 2023 PSAF for Reserve Bank priced services is $23.7 million.[6] This amount represents an increase of $4.3 million from the 2022 PSAF of $19.4 million. This increase is attributable to a $2.6 million increase in the cost of capital primarily driven by rising interest rates, a $1.1 million increase in sales tax, and a $0.6 million increase in Board of Governors expenses.

3. *2023 Projected Performance*—The Reserve Banks project a priced services cost recovery rate of 100.2 percent in 2023, with a net gain of $9.6 million and

2023). See ''Federal Reserve Actions to Support Interbank Settlement of Instant Payments,'' 84 FR 39297, (August 9, 2019). *Available at https://www.govinfo.gov/content/pkg/FR-2019-08-09/pdf/2019-17027.pdf.*

[5] The Fedwire Securities Service over-recovery position is primarily driven by lower-than-budgeted operating and pension costs forecasted for 2022.

[6] Inclusive of the FedNow Service, the PSAF increases to $27.4 million for 2023. In alignment with its 2019 Notice related to the FedNow Service, fees that will be introduced in 2023 are based on costs in a mature volume environment. These costs include PSAF-related expenses the service has incurred over time.

targeted ROE of $8.4 million.[7] The Reserve Banks project that each of the individual service lines will achieve full cost recovery in 2023 except for the Fedwire Funds Service and the National Settlement Service. The Fedwire Funds Service and the National Settlement Service are expected to under recover because of ongoing technology investments, higher operating costs, and a strategy of providing price stability to customers during a period of rising costs.

The Reserve Banks' primary risks to current projections are unanticipated volume and revenue reductions and the potential for cost overruns from new and ongoing improvement initiatives.

4. *2023 Pricing*—The following summarizes the Reserve Banks' proposed changes to fee schedules for priced services in 2023:

Check

- The Reserve Banks will increase the check Participation Fee by $20 to $100 depending on the tier.
- The Reserve Banks will increase check Premium Delivery Fees in the FedReceipt® suite of offerings for 8:00 a.m. ET target fees by $0.005, from $0.032 to $0.037, 10:00 a.m. local target fees by $0.002, from $0.020 to $0.022, and noon local target fees by $0.001, from $0.015 to $0.016.
- The Reserve Banks will increase check Reject Repair Fees by $0.05 for both basic and premium users.
- The Reserve Banks will increase all check FedImage® product fees by 10 percent.
- The Reserve Banks will increase forward paper fees for Canadian cash letter fees for U.S. and Canadian funds by $2.00 and per-item fees by $0.50, Canadian Amount Encoding per-item fee by $0.35, Foreign GBP and EURO per-item fee by $3.00, Foreign All Other per-item fee by $3.00, Foreign Collection per-item fee by $7.00, and the Mixed Forward Products cash letter fee by $2.00 and per-item fee by $0.50.
- The Reserve Banks will increase return paper fees for Large Dollar Return Item Notification (LDRIN) via the FedLine Web® access solution per-item fee by $0.50, Return Item Reclear cash letter fee by $1.00 and per-item fee by $0.05, Qualified and Unqualified Return Item cash letter fee by $2.00 and per-item fee by $1.00, and the Return Item Qualification per-item fee by $1.75.

FedACH

- The Reserve Banks will add a new fifth tier to the FedACH Receipt Discount offered to Premium Receiver at a volume threshold of 30 million items per month. The discount for the new tier increases the current highest discount by $0.0003 to $0.0023 per-item for Premium Receivers, Level One[8] and to $0.0024 per-item for Premium Receivers, Level Two.[9]
- The Reserve Banks will increase the FedACH Participation fee from $65 to $75 per routing transit number (RTN) per month.
- The Reserve Banks will introduce a tiered FedACH Settlement Fee structure with fees ranging from $60 to $200 per RTN per month, based on Premium Receiver status.
- The Reserve Banks will increase the FedACH Information File Extract Fee from $150 to $180 per month.
- The Reserve Banks will increase the International ACH Transaction (IAT) File Fee from $75 to $150 per month.
- The Reserve Banks will increase the FedACH Risk® Management Services Package Fees approximately 20 percent per month depending on the tier.
- The Reserve Banks will introduce a monthly tiered FedACH Exception Resolution Service fee structure with fees ranging from $20 to $500 per month based on monthly case volume count.

Fedwire Funds

- The Reserve Banks will increase the tier 1 volume-based pre-incentive transfer fee from $0.88 to $0.92.
- The Reserve Banks will increase the tier 2 volume-based pre-incentive transfer fee from $0.255 to $0.285.
- The Reserve Banks will increase the tier 3 volume-based pre-incentive transfer fee from $0.17 to $0.18.
- The Reserve Banks will increase the surcharge for offline transfers from $70 to $75.

National Settlement Service

- The Reserve Banks will keep prices at existing levels for all priced National Settlement Service products.

Fedwire Securities

- The Reserve Banks will decrease the agency transfer fee from $0.77 to $0.61.
- The Reserve Banks will decrease the Treasury transfer fee from $0.77 to $0.61.
- The Reserve Banks will decrease the issue maintenance fee from $0.77 to $0.61.
- The Reserve Banks will transition the transfer and settlement of marketable Treasury bills, notes, and bonds over the Fedwire Securities Service from a fiscal agency service to a priced service.
- The Reserve Banks will introduce Fedwire Securities Lending claims adjustment fees to mortgage-backed securities (MBS), Treasury, and non-Treasury debt securities through the Automated Claims Adjustment Process (ACAP) enhancements, expanding ACAP eligibility to all coupon paying securities. Further, the ACAP enhancements will establish two new fees in the schedule.[10]

FedNow Service

- The Reserve Banks will introduce a customer credit transfer and customer credit transfer return fee of $0.045 per-item. Customer credit transfers up to 2,500 transactions will be discounted to $0.00 in 2023 per RTN per month.
- The Reserve Banks will introduce a FedNow participation fee of $25.00 per RTN per month. This fee will be discounted to $0.00 in 2023 per RTN per month.
- The Reserve Banks will introduce a Request for Payment (RFP) fee of $0.01 per-item.
- The Reserve Banks will introduce a Liquidity Management Transfer fee of $1.00 per transfer.

FedLine® Solutions

- The Reserve Banks will discontinue FedMail® Fax Service by December 31, 2023.
- The Reserve Banks will introduce a flat fee assessment for FedMail® Fax Service of $200 per month.
- The Reserve Banks will increase the price for FedMail Email Service (for customers with FedLine Web and above) from $60 to $85.
- The Reserve Banks will increase the price for FedMail Subscribers from $15 to $25.
- The Reserve Banks will discontinue FedComplete® 100 Command Plus and FedComplete 200 Command Plus.
- The Reserve Banks will increase the price for FedComplete 100 Advantage

[7] The FedNow Service will be available mid-2023. Per its 2019 Notice ''Federal Reserve Actions to Support Interbank Settlement of Faster Payments'' (''2019 Notice''), the Board has determined that it is most appropriate to report FedNow Service cost recovery independently of mature priced services until the service has relatively stable revenues and costs. Thus, FedNow Service cost and revenue is excluded from overall performance projections for 2023. See ''Federal Reserve Actions to Support Interbank Settlement of Faster Payments,'' 4 FR 39297, (August 9, 2019). Available here: **Federal Register**:: Federal Reserve Actions To Support Interbank Settlement of Faster Payments.

[8] RDFIs receiving through FedACH at least 90 percent of their FedACH-originated items, but less than 90 percent of all of their ACH items originated through any operator.

[9] RDFIs receiving through FedACH at least 90 percent of all of their ACH items originated through any operator.

[10] The two new fees in the schedule are (1) Repo and Securities Lending Tracking Indicators and (2) Repo and Securities Lending Position Maintenance.

Plus from $825 to $900 and FedComplete 100 Advantage Premier from $900 to $975.

- The Reserve Banks will increase the price for FedComplete 200 Advantage Plus from $1,350 to $1,425 and FedComplete 200 Advantage Premier from $1,425 to $1,500.
- The Reserve Banks will introduce a flat fee assessment for legacy VPN devices of $400 per month to customers who have not started the migration by October 1, 2023.
- The Reserve Banks will collect FedLine Direct fees from FedLine Direct, Check 21 Large File Delivery and other FedLine Command or FedLine Advantage customers that use a wide area network connection.

B. *Private-Sector Adjustment Factor*—The imputed debt financing costs, targeted ROE, and effective tax rate are based on a U.S. publicly traded firm market model.[11] The method for calculating the financing costs in the PSAF requires determining the appropriate imputed levels of debt and equity and then applying the applicable financing rates. In this process, a pro forma balance sheet using estimated assets and liabilities associated with the Reserve Banks' priced services is developed, and the remaining elements that would exist are imputed as if these priced services were provided by a private business firm. The same generally accepted accounting principles that apply to commercial-entity financial statements apply to the relevant elements in the priced services pro forma financial statements.

The portion of Federal Reserve assets that will be used to provide priced services during the coming year is determined using information about actual assets and projected disposals and acquisitions. The priced portion of these assets is determined based on the allocation of depreciation and amortization expenses of each asset class. The priced portion of actual Federal Reserve liabilities consists of postemployment and postretirement benefits, accounts payable, and other liabilities. The priced portion of the actual net pension asset or liability is also included on the balance sheet.[12]

The equity financing rate is the targeted ROE produced by the capital asset pricing model (CAPM). In the CAPM, the required rate of return on a firm's equity is equal to the return on a risk-free asset plus a market risk premium. The risk-free rate is based on the three-month Treasury bill; the beta is assumed to be equal to 1.0, which approximates the risk of the market as a whole; and the market risk premium is based on the monthly returns in excess of the risk-free rate over the most recent 40 years. The resulting ROE reflects the return a shareholder would expect when investing in a private business firm.

For simplicity, given that federal corporate income tax rates are graduated, state income tax rates vary, and various credits and deductions can apply, an actual income tax expense is not explicitly calculated for Reserve Bank priced services. Instead, the Board targets a pretax ROE that would provide sufficient income to fulfill the priced services' imputed income tax obligations. To the extent that performance results are greater or less than the targeted ROE, income taxes are adjusted using the effective tax rate.

Capital structure. The capital structure is imputed based on the imputed funding need (assets less liabilities), subject to minimum equity constraints. Short-term debt is imputed to fund the imputed short-term funding need. Long-term debt and equity are imputed to meet the priced services long-term funding need at a ratio based on the capital structure of the U.S. publicly traded firm market. The level of equity must meet the minimum equity constraints, which follow the FDIC requirements for a well-capitalized institution. The priced services must maintain equity of at least 5 percent of total assets and 10 percent of risk-weighted assets.[13] Any equity imputed that exceeds the amount needed to fund the priced services' assets and meet the minimum equity constraints is offset by a reduction in imputed long-term debt. When imputed equity is larger than what can be offset by imputed debt, the excess is imputed as investments in Treasury securities; income imputed on these investments reduces the PSAF.

Application of the Payment System Risk (PSR) Policy to the Fedwire Funds Service. The Board's PSR policy incorporates the international standards for financial market infrastructures (FMIs) developed by the Committee on Payments and Market Infrastructure and the Technical Committee of the International Organization of Securities Commissions in the *Principles for Financial Market Infrastructures.*[14] The policy requires that the Fedwire Funds Service meet or exceed the applicable risk-management standards. Principle 15 states that an FMI should identify, monitor, and manage general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that it can continue operations and services as a going concern if those losses materialize. Further, liquid net assets should at all times be sufficient to ensure a recovery or orderly wind-down of critical operations and services. The Fedwire Funds Service does not face the risk that a business shock would cause the service to wind down in a disorderly manner and disrupt the stability of the financial system. To foster competition with private-sector FMIs, however, the Reserve Banks' priced services will hold an amount equivalent to six months of the Fedwire Funds Service's current operating expenses as liquid financial assets and equity on the pro forma balance sheet.[15] Current operating expenses are defined as normal business operating expenses on the income statement, less depreciation, amortization, taxes, and interest on debt. Using the Fedwire Funds Service's preliminary 2023 budget, six months of current operating expenses would be $69.5 million. In 2023, $49.9 million of equity was imputed to meet the FDIC capital requirements. Additional equity of $19.7 million was necessary to meet the PSR policy requirement.

Effective tax rate. Like the imputed capital structure, the effective tax rate is calculated based on data from U.S. publicly traded firms. The tax rate is the mean of the weighted average rates of the U.S. publicly traded firm market over the past five years.

Debt and equity financing. The imputed short- and long-term debt financing rates are derived from the nonfinancial commercial paper rates from the Federal Reserve Board's H.15 Selected Interest Rates release (AA and

[11] Data for U.S. publicly traded firms is from the Standard and Poor's Compustat® database. This database contains information on more than 6,000 U.S. publicly traded firms, which approximates information for the entirety of the U.S. market.

[12] The pension assets are netted with the pension liabilities and reported as a net asset or net liability as required by ASC 715 *Compensation—Retirement Benefits.*

[13] The FDIC rule, which was adopted as final on April 14, 2014, requires that well-capitalized institutions meet or exceed the following standards: (1) total capital to risk-weighted assets ratio of at least 10 percent, (2) tier 1 capital to risk-weighted assets ratio of at least 8 percent, (3) common equity tier 1 capital to risk-weighted assets ratio of at least 6.5 percent, and (4) a leverage ratio (tier 1 capital to total assets) of at least 5 percent. Because all of the Federal Reserve priced services' equity on the pro forma balance sheet qualifies as tier 1 capital, only requirements 1 and 4 are binding. The FDIC rule can be located at 12 CFR 324.403(b).

[14] The Committee on Payments and Market Infrastructure was formerly the Committee on Payment and Settlement Systems.

[15] This requirement does not apply to the Fedwire Securities Service. There are no competitors to the Fedwire Securities Service that would face such a requirement, and imposing such a requirement when pricing the securities services could artificially increase the cost of these services.

A2/P2) and the annual Merrill Lynch Corporate & High Yield Index rate, respectively. The equity financing rate is described above. The rates for debt and equity financing are applied to the priced services estimated imputed short-term debt, long-term debt, and equity needed to finance short- and long-term assets and meet equity requirements.

The 2023 PSAF is $23.7 million, compared with $19.4 million in 2022. The increase of $4.3 million is attributable to a net $2.6 million increase in the cost of capital, a $1.1 million increase in sales tax due to inflation, and a $0.6 million increase in Board of Governors expenses. The net $2.6 million increase in cost of capital is primarily driven by a $2.0 million increase in return on equity imputed to satisfy FDIC requirements of a well-capitalized institution and rising interest rates resulting in a $1.2 million increase in cost of debt.

The PSAF expense of $23.7 million, detailed in table 5, reflects $11.6 million for capital funding, $6.8 million for BOG expense, and $5.3 million in sales tax expense.

As shown in table 3, 2023 total assets of $805.6 million increased by $15.5 million from 2022. The net increase in total assets reflects and additional $25.2 million long-term assets partially offset by a net $9.7 million decrease in short-term assets and imputed investments.

The net long-term asset increase of $25.2 million primarily consists of a $25.1 million increase in the net pension asset, reflecting higher plan contributions planned for 2022 and for 2023. In addition to this, Bank premises, furniture and equipment, and software and tenant improvement reflect a combined increase of $19.8 million as a result of additional assets allocated to the priced services. The decrease in the deferred tax asset is due to a change in the discount rate.

The decrease in the short-term assets is primarily driven by a $34.7 million decrease in the imputed investments in Treasury securities from imputed equity required to meet FDIC capital requirements for a well-capitalized institution and to comply with the PSR policy, partially offset by a $10.0 million increase in imputed investments in Fed Funds.

The capital structure of the 2023 pro forma balance sheet, provided in table 4, is composed of equity of $69.5 million, or 13.9 percent of the 2023 risk-weighted assets detailed in table 6, and no long-term debt. The 2023 capital structure differs from that of 2022, which was composed of $77.6 million of equity and no long-term debt. Provided in table 5, the 2023 initially imputed equity required to fund assets and meet the publicly traded firm model capital requirements is $1.0 million. As long-term assets are marginally greater than long-term liabilities, long-term debt of $1.4 million was imputed at the observed market ratio of 59.1 percent. To meet the FDIC capital requirements for a well-capitalized institution, $1.4 million of imputed long-term debt was substituted for equity, and additional equity of $48.9 million was imputed to meet the FDIC capital requirements. The resulting $49.9 million total level of equity was not sufficient to satisfy the $69.5 million equity needed for the PSR policy requirements, and additional equity of $19.7 million was imputed.

The net Accumulated Other Comprehensive loss is $640.8 million, compared with $687.7 million in 2022. The $46.9 million increase is primarily attributable to a higher discount rate. AOCI is in a net loss position and does not reduce the total imputed equity required to fund priced services assets or fulfill the FDIC equity requirements for a well-capitalized institution.

TABLE 3—COMPARISON OF PRO FORMA BALANCE SHEETS FOR BUDGETED FEDERAL RESERVE PRICED SERVICES [a]

[Millions of dollars—projected average for year]

	2023	2022	Change
Short-term assets:			
Receivables	$41.9	$39.0	$2.8
Inventory	0.2	0.4	(0.2)
Prepaid expenses	30.9	30.5	0.4
Items in process of collection [16]	76.0	64.0	12.0
Total short-term assets	148.9	133.9	15.1
Imputed investments: [17]			
Imputed investment in Treasury Securities	67.2	101.9	(34.7)
Imputed investment in Fed Funds	182.0	172.0	10.0
Total imputed investments	249.2	273.9	(24.7)
Long-term assets:			
Premises [18]	100.0	87.6	12.5
Furniture and equipment	54.2	51.9	2.3
Software and leasehold improvements	69.9	64.8	5.1
Net pension asset	25.9	0.9	25.1
Deferred tax asset	157.4	177.1	(19.7)
Total long-term assets	407.5	382.3	25.2
Total assets	805.6	790.1	15.5
Short-term liabilities:			
Deferred credit items	258.0	236.0	22.0
Short-term debt	47.0	21.6	25.3
Short-term payables	25.9	48.3	(22.3)
Total short-term liabilities	330.9	305.9	25.1
Long-term liabilities:			
Postemployment/postretirement benefits and net pension liabilities [19]	405.2	406.6	(1.4)
Total liabilities	736.1	712.4	23.7

TABLE 3—COMPARISON OF PRO FORMA BALANCE SHEETS FOR BUDGETED FEDERAL RESERVE PRICED SERVICES [a]—Continued

[Millions of dollars—projected average for year]

	2023	2022	Change
Equity [20]	69.5	77.6	(8.1)
Total liabilities and equity	805.6	790.1	15.5

[a] Calculations in this table and subsequent PSAF tables may be affected by rounding.

TABLE 4—IMPUTED FUNDING FOR PRICED-SERVICES ASSETS

[Millions of dollars]

	2023	2022
A. Short-term asset financing:		
Short-term assets to be financed:.		
Receivables	$41.9	$39.0
Inventory	0.2	0.4
Prepaid expenses	30.9	30.5
Total short-term assets to be financed	72.9	69.9
Short-term payables	25.9	48.3
Net short-term assets to be financed	47.0	21.6
Imputed short-term debt financing [21]	47.0	21.6
B. Long-term asset financing:		
Long-term assets to be financed:.		
Premises	100.0	87.6
Furniture and equipment	54.2	51.9
Software and Leasehold Improvements	69.9	64.8
Net pension asset	25.9	0.9
Deferred tax asset	157.4	177.1
Total long-term assets to be financed	407.5	382.3
Postemployment/postretirement benefits and net pension liabilities	405.2	406.6
Net long-term assets to be financed	69.5	77.6
Imputed long-term debt [21].		
Imputed equity [21]	69.5	77.6
Total long-term financing	69.5	77.6

TABLE 5—DERIVATION OF THE 2023 AND 2022 PSAF

[Dollars in millions]

	2023		2022	
	Debt	Equity	Debt	Equity
A. Imputed long-term debt and equity:				
Net long-term assets to finance	$ 2.3	$ 2.3	$ (24.3)	$ (24.3)
Capital structure observed in market	59.1%	40.9%	59.1%	40.9%
Pre-adjusted long-term debt and equity	$ 1.4	$ 1.0	$ (14.3)	$ (9.9)
Equity adjustments: [22].				
Equity to meet capital requirements	.....	49.9	.....	46.8
Adjustment to debt and equity funding given capital requirements [23]	(1.4)	1.4	(14.4)	14.4
Adjusted equity balance	.....	2.3	.....	(24.3)
Equity to meet capital requirements [24]	.....	47.5	.....	71.1
Total imputed long-term debt and equity	$	$ 49.9	$	$ 46.8
B. Cost of capital:				
Elements of capital costs:.				
Short-term debt [25]	$ 47.0 x 2.6% =	$ 1.2	$ 21.6 x 0.1% =	$ 0.0
Long-term debt [25]	− x 3.6% =	.....	− x 3.4% =	.....
Equity [26]	49.9 x 14.9% =	7.4	46.8 x 11.6% =	5.4
.....	.....	$ 8.7	.....	$ 5.4
C. Incremental cost of PSR policy:				

TABLE 5—DERIVATION OF THE 2023 AND 2022 PSAF—Continued

[Dollars in millions]

	2023		2022	
	Debt	Equity	Debt	Equity
Equity to meet policy	$ 19.7 x 14.9% =	$ 2.9	$ 30.8 x 11.6% =	$ 3.6
D. Other required PSAF costs:				
Sales taxes	$ 5.3	.....	$ 4.2	.....
Board of Governors expenses	6.8	.....	6.2	.....
		12.1	.....	10.4
		$ 23.7	.....	$ 19.4
E. Total PSAF:				
As a percent of assets	.....	2.9%	.....	2.5%
As a percent of expenses	.....	3.9%	.....	4.3%
F. Tax rates	.....	19.3%	.....	20.3%

TABLE 6—COMPUTATION OF 2023 CAPITAL ADEQUACY FOR FEDERAL RESERVE PRICED SERVICES

[Dollars in millions]

	Assets	Risk weight	Weighted assets
Imputed investments:			
1-Year Treasury securities [27]	$67.2	.....	$
Federal funds [28]	182.0	0.2	36.4
Total imputed investments	249.2	.....	36.4
Receivables	41.9	0.2	8.4
Inventory	0.2	1.0	0.2
Prepaid expenses	30.9	1.0	30.9
Items in process of collection	76.0	0.2	15.2
Premises	100.0	1.0	100.0
Furniture and equipment	54.2	1.0	54.2
Software and leasehold Improvements	69.9	1.0	69.9
Pension asset	25.9	1.0	25.9
Deferred tax asset	157.4	1.0	157.4
Total	805.6	.....	498.5
Imputed equity:			
Capital to risk-weighted assets	13.9%	.....	.....
Capital to total assets	8.6%	.....	.....

[16] Credit float, which represents the difference between items in process of collection and deferred credit items, occurs when the Reserve Banks debit the paying bank for transactions before providing credit to the depositing bank. Float is directly estimated at the service level.

[17] Consistent with the Board's PSR policy, the Reserve Banks' priced services will hold an amount equivalent to six months of the Fedwire Funds Service's current operating expenses as liquid net financial assets and equity on the pro forma balance sheet. Six months of the Fedwire Funds Service's projected current operating expenses is $69.5 million. In 2023, $19.7 million of equity was imputed to meet the regulatory capital requirements.

[18] Includes the allocation of Board of Governors assets to priced services of $2.7 million for 2023 and $2.1 million for 2022.

[19] Includes the allocation of Board of Governors liabilities to priced services of $1.3 million for 2023 and $1.3 million for 2022.

[20] Includes an accumulated other comprehensive loss of $640.8 million for 2023 and $687.7 million for 2022, which reflects the ongoing amortization of the accumulated loss in accordance with ASC 715. Future gains or losses, and their effects on the pro forma balance sheet, cannot be projected. See table 5 for calculation of requird imputed equity amount.

[21] Imputed short-term debt financing is computed as the difference between short-term assets and short-term liabilities. As presented in table 5, the financing costs of imputed short-term debt, imputed long-term debt and imputed equity are the elements of cost of capital, which contribute to the calculation of the PSAF.

[22] If minimum equity constraints are not met after imputing equity based on the capital structure observed in the market, additional equity is imputed to meet these constraints. The long-term funding need was met by imputing long-term debt and equity based on the capital structure observed in the market (see tables 4 and 6). In 2022, the amount of imputed equity met the minimum equity requirements for risk-weighted assets.

[23] Equity adjustment offsets are due to a shift of long-term debt funding to equity in order to meet FDIC capital requirements for well-capitalized institutions.

[24] Additional equity in excess of that needed to fund priced services assets is offset by an asset balance of imputed investments in treasury securities.

[25] Imputed short-term debt and long-term debt are computed at table 4.

[26] The 2023 ROE is equal to a risk-free rate plus a risk premium (beta * market risk premium). The 2022 after-tax CAPM ROE is calculated as 2.29% + (1.0 * 9.72%) = 12.02%. Using a tax rate of 19.3%, the after-tax ROE is converted into a pretax ROE, which results in a pretax ROE of (12.02%/(1–19.3%)) = 14.88%. Calculations may be affected by rounding.

[27] If minimum equity constraints are not met after imputing equity based on all other financial statement components, additional equity is imputed to meet these constraints. Additional equity imputed to meet minimum equity requirements is invested solely in Treasury securities. The imputed investments are similar to those for which rates are available on the Federal Reserve's H.15 statistical

C. *Check Services*—Table 7 shows the 2021 actual, 2022 forecasted, and 2023 budgeted cost-recovery performance for commercial check services.

TABLE 7—CHECK SERVICES PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (roe)	Targeted roe	Recovery rate after targeted roe
	1	2	3 [1 − 2]	4	5 [1/(2 + 4)]
2021 (actual)	109.9	105.4	4.5	1.1	103.2
2022 (forecast)	110.6	109.1	1.5	1.0	100.4
2023 (budget)	108.2	106.7	1.5	1.3	100.1

1. *2022 Forecast*—The Reserve Banks forecast that check services will recover 100.4 percent of total expenses and targeted ROE, compared with a 2022 budgeted recovery rate of 97.1 percent.

Through August, total commercial forward and total commercial return check volumes were 6.4 percent lower and 18.8 percent greater, respectively, than they were during the same period last year. For full-year 2022, the Reserve Banks estimate that their total forward check volume will decline 7.0 percent (compared with a budgeted decline of 7.4 percent) and their total return check volume will increase 12.7 percent (compared with a budgeted decline of 10.2 percent) from 2021 levels. The Reserve Banks expect that check volumes will continue to decline, although uncertainty remains as to the rate of decline into 2023.[29] In particular, the Reserve Banks' check volumes are expected to decline because of substitution away from checks to other payment instruments.

2. *2023 Pricing*—The Reserve Banks expect check services to recover 100.1 percent of total expenses and targeted ROE. The Reserve Banks project revenue to be $108.2 million, a decline of $2.4 million, or 2.2 percent from the 2022 forecast. Total expenses for check services are projected to be $106.7, a decrease of $2.4 million, or 2.2 percent, from 2022 forecasted expenses.

The Reserve Banks will increase the pricing tiers for the fixed monthly participation fee. In light of the ongoing volume declines and growing costs related to check processing infrastructure, the changes are intended to continue to support revenue stability through fixed fees while minimizing the impact of fee increases on smaller institutions, taking into account higher system utilization costs associated with higher volumes from larger institutions. Table 8 shows the 2023-tiered participation fees.

TABLE 8—CHECK 21 PARTICIPATION FEE STRUCTURE

Tier[30]	Monthly fee
1	$325.00
2	200.00
3	130.00
4	75.00

The Reserve Banks will increase FedReceipt® Premium Delivery Fees for the 8:00 a.m. ET target by $0.005, from $0.032 to $0.037, for the 10:00 a.m. local target by $0.002, from $0.020 to $0.022, and for the noon local target by $0.001, from $0.015 to $0.016. The Reserve Banks will increase Reject Repair fees for both basic and premium users by $0.05.

Additionally, the Reserve Banks will adopt a combination of fixed and variable pricing changes to legacy products and services. These changes are a continuation of targeting products that are in the later stages of the product life cycle to encourage customers to use modern services. First, the Reserve Banks will increase all FedImage® product fees 10 percent and sunset eight services that are no longer used or minimally used.[31] Second, the Reserve Banks will increase cash letter fees for forward Canadian Check Clearing for U.S. funds and Canadian funds by $2.00 (13 percent) and per-item fees by $0.50 (9 percent), Canadian Amount Encoding per-item fees by $0.35 (21 percent), Foreign GBP and EURO per-item fees by $3.00 (14 percent), Foreign All Other per-item fees by $3.00 (14 percent), Foreign Collection per-item fees by $7.00 (8 percent), and the Mixed Forward Products cash letter fees by $2.00 (13 percent) and per-item fees by $0.50 (12 percent). Lastly, the Reserve Banks will increase per-item return paper fees for Large Dollar Return Item Notification (LDRIN) via the FedLine Web access solution by $0.50 (12 percent), Return Item Reclear cash letter fees by $1.00 (10 percent) and per-item fees by $0.05 (5.0 percent to 7.0 percent depending on dollar value levels), Qualified and Unqualified Return Item cash letter fees by $2.00 (13 percent) and per-item fees by $1.00 (14 percent), and the Return Item Qualification per-item fee by $1.75 (21 percent).

As check volumes continue to decline, the proposed pricing increases are intended to help stabilize check revenues, to shift the revenue mix toward fixed fees, and to continue a value-based pricing strategy for financial institutions that use the services.

The Reserve Banks estimate the above price changes, along with an expected decrease in volume, will result in an overall 4.5 percent average price increase for check services' customers.

The Reserve Banks' primary risk to current projections for check services is

release, which can be located at *http://www.federalreserve.gov/releases/h15/data.htm.*

[28] The investments are imputed based on the amounts arising from the collection of items before providing credit according to established availability schedules.

[29] Return rates (as a percentage of forward volume) dropped dramatically in 2020 and 2021, likely because of the three rounds of Economic Impact Payments (EIPs) and other federal and state programs in response to the pandemic. Reserve Banks expected these lower rates to continue in 2022, but instead have seen return rates relative to forward volume revert to pre-Covid levels.

[30] This fee is charged to financial institutions that have received any Check 21 electronic or substitute check volume (forward or return) from the Reserve Banks during the month. The fee is applied at the parent financial institution level, as defined in the Reserve Banks' Global Customer Directory. Each financial institution's tier assignment is determined by the criteria described in the FedForward Standard Endpoint Tier Listing.

[31] The following FedImage Services will be discontinued: image capture + 7 business day archive, image capture on-us surcharge, dual archive (transition period up to 120 days), extended dual archive (more than 120 days), reoccurring request retrievals to email via FedLine web, CD–ROM—tape, CD–ROM selected accounts service–RAID, and information retrieval—FedLine (non-image).

a greater-than-expected decline in check volume due to the general reduction in check writing and competition from correspondent banks, aggregators, and direct exchanges, which would result in lower-than-anticipated revenue.

D. *FedACH® Services*—Table 9 shows the 2021 actual, 2022 forecasted, and 2023 budgeted cost-recovery performance for commercial FedACH Services.

TABLE 9—FEDACH SERVICES PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (roe)	Targeted roe	Recovery rate after targeted roe
	1	2	3 [1 − 2]	4	5 [1/(2 + 4)]
2021 (actual)	165.7	167.5	(1.7)	1.7	98.0
2022 (forecast)	173.1	167.6	5.5	1.5	102.3
2023 (budget)	178.6	175.2	3.5	2.2	100.7

1. *2022 Forecast*—The Reserve Banks forecast that FedACH Services will recover 102.3 percent of total expenses and targeted ROE, compared with a budgeted recovery rate of 100.4 percent.

Through August, FedACH commercial origination and receipt volume was 3.9 percent higher than it was during the same period last year. For the full year 2022, the Reserve Banks estimate that FedACH commercial origination and receipt volume will increase 2.9 percent from 2021 levels, compared with a 2021 budgeted increase of 4.9 percent.

2. 2023 *Pricing*—The Reserve Banks expect FedACH Services to recover 100.7 percent of total expenses and targeted ROE in 2023. The Reserve Banks project revenue to be $178.6 million, an increase of $5.5 million, or 3.2 percent, from the 2022 forecast. Total expenses are projected to be $175.2 million, an increase of $7.6 million, or 4.5 percent, from the 2022 forecast.

The Reserve Banks will add a new fifth tier to the ACH Receipt Discount offered to Premium Receiver customers at a volume threshold of 30 million items per month. The new discount tier increases the current highest discount by $0.0003 to $0.0023 per-item for Premium Receivers, Level One and to $0.0024 per-item for Premium Receivers, Level Two.[32]

The Reserve Banks will increase the monthly ACH Participation Fee from $65 to $75 per RTN per month. In addition, the Reserve Banks will introduce a tiered ACH Settlement Fee structure with fees ranging from $60 to $200 per RTN per month based on Premium Receiver status.[33] Over the past years, the Reserve Banks have made minimal changes to existing FedACH Participation and Settlement Fees.[34] The price changes are driven by ongoing operational costs and increased costs associated with introducing three additional intraday settlement windows to FedACH, and reflect higher utilization costs associated with higher volumes.

The Reserve Banks will increase the monthly FedACH Information File Extract Fee from $150 to $180 per month. In addition, the Reserve Banks will increase the IAT File Fee from $75 to $150 per month, and the FedACH Risk® Package Fees approximately 20 percent depending on the tier. The price changes reflect ongoing technology investments and infrastructure enhancements along with minimal price increases for these value-added services in previous years.[35]

The Reserve Banks will modify the existing FedACH Exception Resolution Service fee structure and introduce a monthly fee tiered by usage and consolidated at the parent Depository Financial Institution level. Fees will range from $20 to $500 depending on monthly case volume count. The new tiered fee structure will simplify the current pricing structure by replacing existing fixed monthly and variable per case fees.

The Reserve Banks estimate the above price changes will result in a 4.4 percent average price increase for FedACH customers.

The Reserve Banks will continue to assess pricing strategies that balance price stability with ongoing investments in system enhancements, while responding to economic and market dynamics. The Reserve Banks' primary risks to current projections for FedACH Services are unanticipated cost overruns associated with continued technology and resiliency investments, and lower-than-projected volumes and growth due to the market and economic environment.

E. *Fedwire® Funds Service and National Settlement Service*—Table 10 shows the 2021 actual, 2022 forecasted, and 2023 budgeted cost-recovery performance for the Fedwire Funds Service and the National Settlement Service.

[32] Premium Receivers, Level One: RDFIs receiving through FedACH at least 90 percent of their FedACH-originated items, but less than 90 percent of all of their ACH items originated through any operator. Premium Receivers, Level Two: RDFIs receiving through FedACH at least 90 percent of all of their ACH items originated through any operator.

[33] Premium Receivers will be subject to a settlement fee of $60 per RTN per month. Non-Premium Receivers with a volume threshold of less than 1,500,000 items per month will be subject to a settlement fee of $100 per RTN per month. Non-Premium Receivers with a volume threshold of more than 1,500,000 items per month will be subject to a settlement fee of $200 per RTN per month.

[34] The last increase to the FedACH Participation Fee was in 2018, from $58 to $65, or 12 percent. The last increase to the FedACH Settlement Fee was in 2014, from $50 to $55, or 10 percent.

[35] The last increase to the FedACH Information File Extract Fee was in 2017, from $100 to $150. The last increase to the IAT File Fee was in 2012, from $50 to $75. The FedACH Risk Package Fee has not been increased since it was first introduced in 2013.

TABLE 10—FEDWIRE FUNDS SERVICE AND NATIONAL SETTLEMENT SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (roe)	Targeted roe	Recovery rate after targeted roe
	1	2	3 [1 − 2]	4	5 [1/(2 + 4)]
2021 (actual)	152.7	153.4	(0.7)	1.5	98.6
2022 (forecast)	161.7	158.7	3.0	4.3	99.2
2023 (budget)	164.4	164.0	0.4	4.3	97.7

1. *2022 Forecast*—The Reserve Banks forecast that the Fedwire Funds Service and the National Settlement Service will recover 99.2 percent of total expenses and targeted ROE, compared with a budgeted recovery rate of 100.3 percent.

Through August, Fedwire Funds Service online volume was 1.4 percent lower than it was during the same period last year. For full-year 2022, the Reserve Banks estimate that Fedwire Funds Service online volume will increase 0.1 percent from 2021 levels, compared with the 12.9 percent volume increase that had been budgeted. Through August, the National Settlement Service settlement file volume was 2.9 percent higher than it was during the same period last year, and settlement entry volume was 1.4 percent higher. For full-year 2022, the Reserve Banks estimate that settlement file volume will increase 1.1 percent (compared with a budgeted decrease of 3.1 percent) and settlement entry volume will decrease 0.1 percent from 2021 levels (compared with a budgeted 2.6 percent decrease).

2. *2023 Pricing*—The Reserve Banks expect the Fedwire Funds Service and the National Settlement Service to recover 97.7 percent of total expenses in 2023. Revenue is projected to be $164.4 million, an increase of 1.7 percent from the 2022 forecast. The Reserve Banks project total expenses to be approximately $5.3 million higher than 2022 expenses, an increase of 3.3 percent, primarily reflecting ongoing technology investments, including those associated with the Fedwire Funds Service's transition to the ISO® 20022 messaging format.[36] In addition, the National Settlement Service incurred higher costs in 2022 because of the expansion of its operating hours.[37]

The Reserve Banks will increase all three of the gross origination and receipt tiered fees. The tier 1 fee will increase from $0.88 to $0.92, the tier 2 fee will increase from $0.255 to $0.285, and the tier 3 fee will increase from $0.17 to $0.18. In addition, the offline send and receive surcharge for the Fedwire Funds Service will increase from $70.00 to $75.00. The Reserve Banks estimate the above price changes will result in an overall 8.3 percent average price increase for Fedwire Funds Service customers.

The Reserve Banks will not change National Settlement Service fees for 2023.

The Reserve Banks' primary risk to current projections for these services is uncertainty about the economic outlook for 2023, which complicates the accuracy of 2023 volume projections. Historically, Fedwire Funds Service volume has reflected market conditions, and a broader downturn in 2023 would likely result in a decrease in Fedwire Funds Service volume.[38] Separately, unexpected increases in 2023 technology costs would likely result in reduced cost recovery for the year.

F. *Fedwire Securities Service*—Table 11 shows the 2021 actual, 2022 forecast, and 2023 budgeted cost-recovery performance for the Fedwire Securities Service.[39]

TABLE 11—FEDWIRE SECURITIES SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (roe)	Targeted roe	Recovery rate after targeted roe
	1	2	3 [1 − 2]	4	5 [1/(2 + 4)]
2021 (actual)	27.7	26.5	1.2	0.2	103.8
2022 (forecast)	24.7	22.6	2.1	0.2	108.4
2023 (budget)	44.5	40.3	4.3	0.5	109.3

[36] In October 2021, the Board announced that the Federal Reserve Banks will adopt the ISO 20022 message format for the Fedwire® Funds Service. *See* New Message Format for the Fedwire Funds Services, 86 FR 55600 (June 27, 2022). Available at **Federal Register** Notice: New Message Format for the Fedwire Funds Service (*federalreserve.gov*).

[37] The National Settlement Service expanded its hours to 21.5 hours per day in 2022, with a new 9:00 p.m. ET open for the next business day.

[38] Fedwire Funds Service volume growth reflects economic growth. For example, its volume has grown every year except for 2008 and 2009, when it contracted 2.5 percent and 5.0 percent, respectively, during the Great Recession. For historical Fedwire Funds Service volume data, see frbservices.org, ''Fedwire Funds Service—Annual Statistics. Available at: *https://www.frbservices.org/resources/financial-services/wires/volume-value-stats/annual-stats.html.*

[39] The Reserve Banks provide transfer services for securities issued by the U.S. Treasury, federal government agencies, government-sponsored enterprises, and certain international institutions. The priced component of this service, reflected in this memorandum, consists of revenues, expenses, and volumes associated with the transfer of all non-Treasury securities. For Treasury securities, the U.S. Treasury assesses fees for the securities transfer component of the service. The Reserve Banks assess a fee for the funds settlement component of a Treasury securities transfer; this component is not treated as a priced service.

1. *2022 Forecast*—The Reserve Banks forecast that the Fedwire Securities Service will recover 108.4 percent of total expenses and targeted ROE, compared with a 2022 budgeted recovery rate of 149.4 percent.

For full-year 2022, volume for account maintenance is expected to decline from 2021 levels, while volumes for issue maintenance are expected to increase modestly from 2021 levels. Through August, account maintenance volume was 2.9 percent lower than it was during the same period last year. For full-year 2022, the Reserve Banks estimate that account maintenance volume will decline 3.2 percent from 2021 levels, compared with a budgeted decline of 4.6 percent. Through August, the number of agency issues maintained was 2.0 percent higher than it was during the same period last year. For full-year 2022, the Reserve Banks estimate that the number of agency issues maintained will increase 2.2 percent from 2021 levels, compared with a budgeted decline of 0.6 percent.

2. *2023 Pricing*—The Reserve Banks expect the Fedwire Securities Service to recover 109.3 percent of total expenses and targeted ROE in 2023. Revenue is projected to be $44.5 million, an increase of 80.2 percent from the 2022 revenue forecast. The Reserve Banks also project that 2023 expenses will increase by $17.7 million from the 2022 forecast, an increase of 78.3 percent.

The Reserve Banks project that agency transfer volume will remain relatively stable compared with previous years, with no notable changes that could potentially have a significant impact on agency transfers. The volume of Treasury security transfers is projected to increase because of anticipated growth of public debt. The volume of accounts maintained are expected to decrease 3.0 percent, consistent with recent trends and primarily driven by a reduction in joint custody accounts. The volume of agency issues maintained is expected to remain relatively flat, driven by expectations that security holdings will become increasingly concentrated and the volume of MBS CUSIPs on priced Securities Accounts will continue to increase. Claim adjustment volume is expected to increase with enhancements to the ACAP product. The Reserve Banks will decrease the agency transfer fee, the Treasury transfer fee, and the issue maintenance fee from $0.77 to $0.61 as part of a strategic transition to more accurately align costs across product offerings and to adjust for the large over-recovery in 2022.

In response to direction from the U.S. Department of the Treasury, the Reserve Banks will offer to participants the transfer and settlement of marketable Treasury bills, notes, and bonds over the Fedwire Securities Service as a priced service effective January 3, 2023. This will align the Reserve Banks' treatment of transfer and settlement of Treasury securities with its treatment of transfer and settlement of non-Treasury securities.[40]

Following the transition of transfer services for Treasury securities to a priced service, the Reserve Banks will set, charge, collect, and retain fees from customers for transfers of Treasury securities, obviating the need for remittance to and reimbursement from the U.S. Department of the Treasury.

As part of the ACAP enhancements, the Reserve Banks are introducing several changes to ACAP pricing.

First, the Reserve Banks will introduce the pricing of applicable claim adjustments on newly ACAP-eligible security types, Treasury securities, and non-Treasury debt securities, as part of the implementation of the ACAP enhancement project in 2023. The ACAP enhancements will add a new claim type, Securities Lending, to the existing claim adjustments. This change will result in an extension of the pricing schedule to Securities Lending claim adjustments for MBS, Treasury, and non-Treasury debt securities.

Further, the Reserve Banks will expand the existing ACAP's pricing schedule to include Repo Tracking Indicators and Repo Position Maintenance fees, and once available, to Securities Lending Tracking Indicators and Securities Lending Position Maintenance fees.

The Reserve Banks estimate the above price changes will result in an overall 17.3 percent average price decrease for Fedwire Funds Service customers.

The Reserve Banks' primary risks to current projections for the Fedwire Securities Service include variations in technology costs and product volume forecasts stemming from an uncertain economic outlook.

G. FedNow Service

1. *2022 Forecast*—The Reserve Banks did not estimate FedNow Service recovery of total expenses and targeted ROE because it will not be operational until mid-2023.

2. *2023 Pricing*—The Reserve Banks will introduce a fee schedule for the FedNow Service that includes both per-item and fixed fees. This represents the initial fee schedule for the service, and the Reserve Banks expect that the fee schedule will change as the service matures.

To limit prohibitively high or unnecessarily volatile prices, fees are based on transaction costs associated with mature volume estimates, inclusive of PSAF related expenses. This approach is similar to how the Reserve Banks have set fees for new services in the past.[41] The proposed fee schedule also reflects the Federal Reserve's assessment of prevailing market practices among instant payments operators. Additionally, as described in greater detail below, the FedNow Service will discount certain fees to $0.00 in 2023. This approach is in alignment with the Board's Pricing Principles and will support the Board's policy objective of nationwide access to instant payments.[42]

The Reserve Banks will introduce a per-item fee of $.045 that is charged to the FedNow Sender for each customer credit transfer (CCT) and CCT return.[43] These fees will only be charged for messages that are accepted by the FedNow Receiver and settled over the service.[44] CCTs up to 2,500 transactions

[40] Currently, the Reserve Banks provide transfer services for Treasury securities as fiscal agent on behalf of the U.S. Department of the Treasury. Fees related to transfers of Treasury securities are set by the U.S. Department of the Treasury and collected by the Reserve Banks. The fees are then remitted to the U.S. Department of the Treasury by the Reserve Banks. The U.S. Department of the Treasury currently reimburses the Reserve Banks for the associated costs.

[41] In establishing fees for the Federal Reserve's ACH service, the Board allowed fees to be set to recover costs associated with mature volume estimates instead of current costs. As part of setting fees following the passage of the MCA in 1980, the Federal Reserve published a specific year that it expected ACH to achieve annual cost recovery. At that time, FedACH had been in operation for more than a decade, giving the Federal Reserve the ability to estimate costs and revenues with relative confidence. Performing a similar exercise for the FedNow Service would not be feasible in the short term because of the lack of historical data. See Board of Governors of the Federal Reserve System, ''Adoption of Fee Schedules and Pricing Principles for Federal Reserve Bank Services,'' 46 FR 1338, 1343 (Jan. 6, 1981). Available at: *https://cdn.loc.gov/service/ll/fedreg/fr046/fr046003/fr046003.pdf.*

[42] This approach is consistent with the Board's Pricing Principles. Specifically, in adopting principle 7, the Board explained that pricing flexibility may be necessary to induce desirable long-run changes in the payment system and to foster development of services that will ultimately benefit the public. See ''Policies: The Federal Reserve in the Payments System,'' (January 2001). Available at: Federal Reserve Board—Policies: The Federal Reserve in the Payments System.

[43] Operating Circular (OC) 8 defines a FedNow Sender as a FedNow Participant that sends a payment order through the FedNow Service. ''Operating Circular 8,'' (September 21, 2022). Available at: Operating Circular No. 8—Funds Transfers through the FedNow Service (*frbservices.org*).

[44] OC 8 defines a FedNow Receiver as a FedNow Participant that receives a payment order or Request for Confirmation through the FedNow Service. See ''Operating Circular 8,'' (September 21, 2022).

per RTN per month will be discounted to $0.00 in 2023.

The Reserve Banks will introduce a $25 monthly participation fee, discounted to $0.00 per month in 2023, for every routing transit number (RTN) enrolled in the service. The participation fee will only be charged to RTNs that are able to receive CCTs (Send & Receive or Receive-only participation types). The participation fee will not be charged to Liquidity Management Transfer (LMT) only and Settlement-only participation types in 2023.[45]

The Reserve Banks will introduce a fee of $0.01 that is charged to the FedNow Participant for each request for payment (RFP) message that is completed or received by a financial institution with RFP receipt enabled.[46] RFP messages sent to a financial institution that is not enabled for receipt of RFP will not be assessed the fee, since those messages will not be completed. The fee will be charged regardless of whether the RFP is answered with a CCT.

The Reserve Banks will introduce a fee of $1.00 that is charged to the FedNow Sender for each liquidity management transfer settled over the FedNow Service. Although not currently under consideration, a separate, fixed fee related to LMT use may introduced in the future. Changes to the LMT per-item fee will also be under consideration as LMT activity evolves. Per the 2020 Notice related to the FedNow Service, LMT is designed to support liquidity needs related to instant payments activity more broadly.[47]

H. FedLine Solutions—The Reserve Banks charge fees for the electronic connections that financial institutions use to access priced services and allocate the costs and revenues associated with this electronic access to the priced services.[48] There are six FedLine channels through which customers can access the Reserve Banks' priced services: FedMail®, FedLine Exchange®, FedLine Web®, FedLine Advantage®, FedLine Command® and FedLine Direct®.[49] The Reserve Banks bundle these channels into eleven FedLine packages, described below, that are supplemented by a number of premium (or à la carte) access and accounting information options. In addition, the Reserve Banks offer FedComplete packages, which are bundled offerings of FedLine connections and a fixed number of FedACH Services, Fedwire Funds Service, and Check 21-enabled transactions.

Eight attended-access packages offer manual access to critical payment and information services via a web-based interface. The FedMail package provides access to basic information services via email, while the two FedLine Exchange packages are designed to provide certain services, such as the E-Payments Routing Directory, to customers that otherwise do not use FedLine for any payment services. Two FedLine Web packages offer online attended access to a range of services, including cash services, FedACH information services, and check service. Three FedLine Advantage packages expand upon the FedLine Web packages and offer attended access to critical transactional services: FedACH, Fedwire Funds, and Fedwire Securities. FedLine Advantage will also offer attended access to the FedNow Service when it is operational.

Three unattended access packages are computer-to-computer, internet protocol (IP)-based interfaces. The FedLine Command package offers an unattended connection to FedACH, most accounting information services, and the FedNow Service when it is made available. The two remaining options are FedLine Direct packages, which allow for unattended connections at multiple connection speeds to Check, FedACH, Fedwire Funds, and Fedwire Securities transactional and information services and to most accounting information services. FedLine Direct packages will also allow for unattended connection to the FedNow Service.

The Reserve Banks propose to increase the monthly fees for the FedMail Email Service from $60 to $85, and for FedMail Subscribers from $15 to $25. To provide an incentive for current customers to move to alternatives such as FedLine Web, the Reserve Banks propose to introduce a monthly fee assessment for the FedMail Fax Service of $200 beginning in 2023. The Reserve Banks propose to discontinue the FedMail Fax Service by December 31, 2023. The FedMail Fax Service is available à la carte for all FedLine Solutions access packages, and FedMail Email Service is available à la carte only for FedLine Web or higher packages.[50] The Reserve Banks seek not only to provide highly secure, modern access solutions, but also to enhance the customer experience through access to value-added services not available on legacy technology. Delivery of financial services information, such as transaction advices, accounting reports, and other statements over fax and email, does not align with industry best practices and poses potential risks to the confidentiality of customer information.

The Reserve Banks propose to update all existing FedComplete 100 and 200 packages. The Reserve Banks propose to increase the monthly fee for FedComplete Advantage Plus from $825 to $900, FedComplete 100 Advantage Premier from $900 to $975, FedComplete 200 Advantage Plus from $1,350 to $1,425, and FedComplete 200 Advantage Premier from $1,425 to $1,500. The Reserve Banks propose to discontinue offering FedComplete 100 Plus and FedComplete 200 Command Plus. The proposed price increase aligns with the increase to the Check Monthly Participation fee, FedACH participation and settlement fees, and Fedwire Funds Service fees in alignment with fee changes in this notice. The Reserve Banks are discontinuing FedComplete 100 Command Plus and 200 Command Plus because of low demand, no new customers being onboarded, and a need to streamline offerings to reduce complexity of service and billing.

The Reserve Banks propose to introduce a monthly fee assessment of $400 for legacy VPN devices to customers who have not started the migration by October 1, 2023. VPN devices are a key component of a customer's FedLine Advantage and FedLine Command connections to critical payment and informational services. The purpose of this monthly fee assessment is to support the timely

Available at: Operating Circular No. 8—Funds Transfers through the FedNow Service (*frbservices.org*).

[45] For more information on FedNow participation types, see ''FedNow features: flexible participation types,'' (April 27, 2021). Available at: *https://www.frbservices.org/financial-services/fednow/blog/fednow-features-flexible-participation-types.html.*

[46] A FedNow Participant that sends an RFP message can request either a CCT or a CCT return in response to the message.

[47] LMT will enable participants in the FedNow Service to transfer funds to one another to support liquidity needs related to payment activity in the FedNow Service. LMT will also support participants in a private-sector instant payment service backed by a joint account at a Reserve Bank by enabling transfers between the master accounts of participants and a joint account. See ''Service Details on Interbank Actions to Support Interbank Settlement of Instant Payments,'' 85 FR 48522, (August 11 2020). Available here: *https://www.govinfo.gov/content/pkg/FR-2020-08-11/pdf/2020-17539.pdf.*

[48] FedLine Solutions provide customers with access to Reserve Bank priced services. As such, FedLine costs and revenue are allocated to the Reserve Banks' priced services on an expense ratio basis.

[49] FedMail, FedLine Exchange, FedLine Web, FedLine Advantage, FedLine Command, and FedLine Direct are registered trademarks of the Federal Reserve Banks.

[50] In 2018, the Board of Governors approved a proposal to cease onboarding of new subscribers to the FedMail Fax Service effective January 1, 2019.

completion of the Next Generation Access Solution (NGAS) Virtual Private Network (VPN) migration. As part of the Federal Reserve Banks' ongoing modernization efforts, all customers are required to convert their VPN devices by the end of 2023.

In addition, the Reserve Banks propose that use of a wide area network (WAN) connection for priced services will be associated with, and billed in accordance with, FedLine Direct package fees.[51] As the Reserve Banks support current customers and prepare to launch new services, the FedLine Direct network continues to be the premier solution, with added resiliency, greater security, active monitoring, dedicated bandwidth, and consistent operational support.[52] The Reserve Banks estimate the above price changes will result in a 4.0 percent average price increase for FedLine customers.

Finally, for financial institutions that plan to adopt the FedNow Service in 2023, the Reserve Banks will discount certain FedLine fees to $0.00 to support testing activities and streamlined onboarding processes.[53] More detail regarding discounted FedLine fees will be shared through existing Reserve Bank channels closer to FedNow Service introduction.

II. Analysis of Competitive Effect

All operational and legal changes considered by the Board that have a substantial effect on payment system participants are subject to the competitive impact analysis described in the March 1990 policy ''The Federal Reserve in the Payments System.'' [54] Under this policy, the Board assesses whether changes would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services because of differing legal powers or constraints or because of a dominant market position deriving from such legal differences. If any proposed changes create such an effect, the Board must further evaluate the changes to assess whether the benefits associated with the changes—such as contributions to payment system efficiency, payment system integrity, or other Board objectives—can be achieved while minimizing the adverse effect on competition.

The 2023 fees, fee structures, and changes in service will not have a direct and material adverse effect on the ability of other service providers to compete effectively with the Reserve Banks in providing similar services. The Reserve Banks expect to continue to achieve aggregate long-run cost recovery across all mature priced services.

III. 2023 Fee Schedules

FedACH Services 2023 Fee Schedule

[Effective January 3, 2023. **Bold indicates changes from 2022 prices**]

	Fee
FedACH minimum monthly fee:	
Originating depository financial institution (ODFI) [55]	$50.00.
Receiving depository financial institution (RDFI) [56]	$40.00.
Origination (per item or record):	
Forward or return items	$0.0035.
SameDay Service—forward item [57]	$0.0010 surcharge.
Addenda record	$0.0015.
FedLine Web-originated returns and notification of change (NOC) [58]	$0.50.
Facsimile Exception Return/NOC [59]	$45.00.
SameDay Exception Return	$45.00.
Automated NOC	$0.20.
Volume discounts (based on monthly billed origination volume) [60] per item when origination volume is:.	
750,001 to 1,500,000 items per month discount	$0.0008.
more than 1,500,000 items per month discount	$0.0010.
Volume discounts (based on monthly billed receipt volume) [61] per item when receipt volume is:.	
10,000,001 to 15,000,000 items per month discount	$0.0002.
more than 15,000,000 items per month discount	$0.0003.
Receipt (per item or record):	
Forward Item	$0.0035.
Return Item	$0.0075.
Addenda record	$0.0015.
Volume discounts:.	
Non-Premium Receivers [62] per item when volume is:.	
750,001 to 12,500,000 items per month [63]	$0.0017 discount.
more than 12,500,000 items per month [64]	$0.0019 discount.
Premium Receivers, Level One [65] per item when volume is:.	
750,001 to 1,500,000 items per month [66]	$0.0017 discount.
1,500,001 to 2,500,000 items per month [64]	$0.0017 discount.
2,500,001 to 12,500,000 items per month [64]	$0.0018 discount.
more than 12,500,000 items per month [64]	$0.0020 discount.
more than 30,000,000 items per month [64]	**$0.0023 discount**.
Premium Receivers, Level Two [67] per item when volume is:.	
750,001 to 1,500,000 items per month [68]	$0.0017 discount.
1,500,001 to 2,500,000 items per month [64]	$0.0017 discount.
2,500,001 to 12,500,000 items per month [64]	$0.0019 discount.
more than 12,500,000 items per month [64]	$0.0021 discount.
more than 30,000,000 items per month [64]	**$0.0024 discount**.

[51] In 2019, a redesign of the FedLine Direct product offering was approved, introducing new package and pricing options that affected all FedLine Direct, Check 21 Large File Delivery, and other FedLine Command or FedLine Advantage customers that use a WAN connection.

[52] The Reserve Banks are preparing to deliver services to the industry via Application Programming Interfaces (API). APIs are a set of protocols for connecting software systems programmatically, enabling system-to-system interoperability. Communication will be forthcoming on timing and availability of initial APIs.

[53] Monthly fees for a new VPN device or WAN device to support FedNow Service activity will be discounted to $0.00 in 2023. Fees to set up a new FedLine Solution for the FedNow Service will be discounted to $0.00. Finally, new subscribers that the financial institution adds to support FedNow Service access will not contribute toward the fee for a FedLine Subscriber 5-Pack.

[54] Federal Reserve Regulatory Service (FRRS) 9–1558.

FEDACH SERVICES 2023 FEE SCHEDULE

[Effective January 3, 2023. **Bold indicates changes from 2022 prices**]

	Fee
FedACH Risk Management Services: [69]	
Monthly Package Fee (a single fee based on total number of criteria sets):.	
For up to 5 criteria sets	**$45.00**.
For 6 through 11 criteria sets	**$85.00**.
For 12 through 23 criteria sets	**$150.00**.
For 24 through 47 criteria sets	**$180.00**.
For 48 through 95 criteria sets	**$300.00**.
For 96 through 191 criteria sets	**$510.00**.
For 192 through 383 criteria sets	**$810.00**.
For 384 through 584 criteria sets	**$1,025.00**.
For more than 584 criteria sets	**$1,325.00**.
Batch/Item Monitoring (based on total monthly volume):.	
For 1 through 100,000 batches (per batch)	$0.007.
For more than 100,000 batches (per batch)	$0.0035.
FedPayments Insights Service: [70]	
Monthly Fee (a single fee based on commercial receipt volume):.	
0–50,000 items per month	$75.00.
50,001–100,000 items per month	$120.00.
100,001–500,000 items per month	$180.00.
500,001–1,000,000 items per month	$260.00.
1,000,001–5,000,000 items per month	$340.00.
5,000,001–10,000,000 items per month	$450.00.
10,000,001–25,000,000 items per month	$550.00.
25,000,001–60,000,000 items per month	$625.00.
Over 60,000,000 items per month	$700.00.
Monthly FedPayments Reporter Service:	
FedPayments Reporter Service monthly package includes the following reports.	
ACH Received Entries Detail—Customer and Depository Financial Institution.	
ACH Return Reason Report—Customer and Depository Financial Institution.	
ACH Originated Entries Detail—Customer and Depository Financial Institution.	
ACH Volume Summary by SEC Code—Customer.	
ACH Customer Transaction Activity.	
ACH Death Notification.	
ACH International (IAT).	
ACH Notification of Change.	
ACH Payment Data Information File.	
ACH Remittance Advice Detail.	
ACH Remittance Advice Summary.	
ACH Return Item Report and File.	
ACH Return Ratio.	
ACH Social Security Beneficiary.	
ACH Originator Setup.	
ACH Report Delivery via FedLine Solution.	
On Demand Report Surcharge [71]	$1.00.
Monthly Package Fee (counts reflect reports generated as well as delivered via a FedLine Solution):	
For up to 50 reports	$45.00.
For 51 through 150 reports	$65.00.
For 151 through 500 reports	$120.00.
For 501 through 1,000 reports	$220.00.
For 1,001 through 1,500 reports	$320.00.
For 1,501 through 2,500 reports	$505.00.
For 2,501 through 3,500 reports	$705.00.
For 3,501 through 4,500 reports	$900.00.
For 4,501 through 5,500 reports	$1,095.00.
For 5,501 through 7,000 reports	$1,350.00.
For 7,001 through 8,500 reports	$1,585.00.
For 8,501 through 10,000 reports	$1,815.00.
For more than 10,000 reports	$1,980.00.
Premier reports (per report generated): [71].	
ACH Volume Summary by SEC Code Report—Depository Financial Institution:.	
For 1 through 5 reports	$10.00.
For 6 through 10 reports	$6.00.
For 11 or more reports	$1.00.
On Demand Surcharge	$1.00.
ACH Routing Number Activity Report:.	
For 1 through 5 reports	$10.00.
For 6 through 10 reports	$6.00.
For 11 or more reports	$1.00.
On Demand Surcharge	$1.00.
ACH Originated Batch Report (monthly):.	
For 1 through 5 reports	$10.00.
For 6 through 10 reports	$6.00.
For 11 or more reports	$1.00.
On Demand Surcharge	$1.00.
ACH Originated Batch Report (daily):.	
Scheduled Report	$0.65.
On Demand Surcharge	$1.00.
On-us inclusion:.	
Participation (monthly fee per RTN)	$10.00.
Per-item	$0.0030.

FEDACH SERVICES 2023 FEE SCHEDULE—Continued

[Effective January 3, 2023. **Bold indicates changes from 2022 prices**]

	Fee
Per-addenda	$0.0015.
Report delivery via encrypted email (per email)	$0.20.
Other Fees and Discounts:	
Monthly fee (per RTN):.	
FedACH Participation Fee [72]	**$75.00**.
Same Day Service Origination Participation Fee [73]	$10.00.
FedACH Settlement Fee [74].	
Premium Receivers, Level One [75] **and Level Two** [76]	**$60.00**.
Non-Premium Receivers [77] **when volume is less than 1,500,000 items per month**	**$100.00**.
Non-Premium Receivers [78] **when volume is more than 1,500,000 items per month**	**$200.00**.
FedACH Information File Extract Fee	**$180.00**.
IAT Output File Sort Fee	**$150.00**.
Fixed Participation Fee—Automated NOCs [79]	$5.00.
Non-Electronic Input/Output fee: [80].	
CD/DVD (CD or DVD)	$50.00.
Paper (file or report)	$50.00.
Fees and Credits Established by Nacha: [81].	
Nacha Same Day Entry fee (per item)	$0.052.
Nacha Same Day Entry credit (per item)	$0.052 (credit).
Nacha Unauthorized Entry fee (per item)	$4.50.
Nacha Unauthorized Entry credit (per item)	$4.50 (credit).
Nacha Admin Network fee (monthly fee per RTN)	$22.00.
Nacha Admin Network fee (per entry)	$0.000185.
FedGlobal® ACH Payments: [82]	
Fixed Monthly Fee (per RTN): [83].	
Monthly origination volume more than 500 items	$185.00.
Monthly origination volume between 161 and 500 items	$60.00.
Monthly origination volume less than 161 items	$20.00.
Per-item Origination Fee for Monthly Volume more than 500 Items (surcharge): [84].	
Canada service	$0.50.
Mexico service	$0.55.
Panama service	$0.60.
Europe service	$1.13.
Per-item Origination Fee for Monthly Volume between 161 and 500 items (surcharge): [84].	
Canada service	$0.75.
Mexico service	$0.80.
Panama service	$0.85.
Europe service	$1.38.
Per-item Origination Fee for Monthly Volume less than 161 items (surcharge): [84].	
Canada service	$1.00.
Mexico service	$1.05.
Panama service	$1.10.
Europe service	$1.63.
Other FedGlobal ACH Payments Fees:.	
Canada service:.	
Return received from Canada [85]	$0.99 (surcharge).
Trace of item at receiving gateway	$5.50.
Trace of item not at receiving gateway	$7.00.
Mexico service:.	
Return received from Mexico [85]	$0.91 (surcharge).
Item trace	$13.50.
Foreign currency to foreign currency (F3X) item originated to Mexico [84]	$0.67 (surcharge).
Panama service:.	
Return received from Panama [85]	$1.00 (surcharge).
Item trace	$7.00.
NOC	$0.72.
Europe service:.	
F3X item originated to Europe [84]	$1.25 (surcharge).
Return received from Europe [85]	$1.35 (surcharge).
Item trace	$7.00.
Exception Resolution Service:	
Monthly Fees (applies to cases only at the parent RTN): [86].	
Up to 5 cases	**$20.00**.
6–25 cases	**$40.00**.
26–50 cases	**$60.00**.
51–100 cases	**$100.00**.
101–1,000 cases	**$250.00**.
1,001–5,000 cases	**$400.00**.
5,001 cases and above	**$500.00**.
Offline Service Participant—Case Fees: [87].	
Case Open Fee	$5.00.
Case Response Fee	$5.00.

FEDWIRE FUNDS SERVICE AND NATIONAL SETTLEMENT SERVICE 2023 FEE SCHEDULES

[Effective January 3, 2023. **Bold indicates changes from 2022 prices.**]

	Fee
Fedwire Funds Service	
Monthly Participation Fee	$100.00
Basic volume-based pre-incentive transfer fee (originations and receipts)—per transfer for:	
Tier 1: The first 14,000 transfers per month	**0.920**
Tier 2: Additional transfers up to 90,000 per month	**0.285**
Tier 3: Every transfer over 90,000 per month	**0.180**
Volume-based transfer fee with the incentive discount (originations and receipts)—per eligible transfer for: [88]	
Tier 1: The first 14,000 transfers per month	**0.184**
Tier 2: Additional transfers 14,001 to 90,000 per month	**0.057**
Tier 3: Every transfer over 90,000 per month	**0.036**
Surcharge for Offline Transfers (Originations and Receipt)	**75.00**
Surcharge for End-of-Day Transfer Originations [89]	0.26
Monthly FedPayments Manager Import/Export fee [90]	50.00
Surcharge on transfers >$10 million Origination and Receipt	0.14
Surcharge on transfers >$100 million Origination and Receipt	0.36
Surcharge for Payment Notification:	
Origination Surcharge [91]	0.01
Receipt Volume [91] [92]	N/A
Delivery of Reports—Hard Copy Reports to On-Line Customers	50.00
Special Settlement Arrangements (charge per settlement day) [93]	150.00
National Settlement Service	
Basic:	
Settlement Entry Fee	1.50
Settlement File Fee	30.00
Surcharge for Offline File Origination [94]	45.00
Minimum Monthly Fee [95]	60.00

FEDWIRE SECURITIES SERVICE 2023 FEE SCHEDULE

[Effective January 3, 2023. **Bold indicates changes from 2022 prices.**]

	Fee
Basic Transfer Fee: [96] [97]	
Agency Securities: Transfer or reversal originated or received	**$0.61**
Treasury Securities: Transfer or reversal originated or received	**0.61**
Surcharge: [98]	
Agency Securities: Offline origination & receipt surcharge	80.00
Treasury Securities: Offline origination & receipt surcharge	80.00
Monthly Maintenance Fees: [99]	
Agency Securities: Account maintenance (per account) [100]	57.50
Agency Securities: Issue maintenance (per issue/per account) [101]	**0.61**
Treasury Securities: Account maintenance (per account) [102]	None
Treasury Securities: Issue maintenance (per issue/per account) [103]	None
ACAP Fees: [104] [105]	
Claims Adjustment Fee [106] [107]	1.00
Tracking Indicators Fee	**0.10**
Position Maintenance Fee (per position maintained/per business day) [108] [109]	**0.03**
GNMA Serial Note Stripping or Reconstitution Fee [110]	9.00
Joint Custody Origination Surcharge [111] [112]	46.00
Delivery of Reports—Hard Copy Reports to On-Line Customers [113]	50.00

FEDNOW SERVICE 2023 FEE SCHEDULE

[Effective January 3, 2023. **Bold indicates changes from 2022 prices.**]

	Fee
Customer Credit Transfer (per item) PACS.008 Origination	**$0.045**.
Customer Credit Transfer Returns (per item) PACS.004 Origination	**$0.045**.
Liquidity Management Transfer (LMT) (per-item) PACS.009 Origination	**$1.00**.
Request for Payment (RFP) (per-item) PAIN.013	**$0.01**.
PACS.008 Origination Discount	**−$0.045 per item for up to 2,500 customer credit transfers per month (in 2023)**.
Participation Fee—General (per month)	**$25.00, discounted to $0.00 in 2023**.

FEDLINE 2023 FEE SCHEDULE

[Effective January 3, 2023. **Bold indicates changes from 2022 prices.**]

	Fee
FedComplete Packages (monthly) [114] [115]	
FedComplete 100A Plus [116]	**$900.00**.
includes:	
FedLine Advantage Plus package.	
FedLine Subscriber—Pack of 5.	
7,500 FedForward transactions.	
46 FedForward Cash Letter items.	
70 FedReturn transactions.	
14,000 FedReceipt transactions.	
Check monthly participation fee.	
35 Fedwire Funds origination transfers.	
35 Fedwire Funds receipt transfers.	
Fedwire monthly participation fee.	
1,000 FedACH origination items.	
FedACH monthly minimum fee—Forward Origination.	
7,500 FedACH receipt items.	
FedACH monthly minimum fee—Receipt.	
10 FedACH web-originated return/NOC.	
500 FedACH addenda record originated.	
1,000 FedACH addenda record received.	
100 FedACH SameDay Service—Forward Item Originated.	
FedACH Participation Fee.	
FedACH settlement fee.	
FedACH SameDay Service origination participation fee.	
FedComplete 100A Premier	$975.00.
includes:	
FedLine Advantage Premier package.	
Volumes included in the FedComplete 100A Plus package.	
FedComplete 200A Plus	**$1,425.00**.
includes:	
FedLine Advantage Plus package.	
FedLine subscriber 5-pack.	
25,000 FedForward transactions.	
46 FedForward Cash Letter items.	
225 FedReturn transactions.	
25,000 FedReceipt transactions.	
Check monthly participation fee.	
100 Fedwire Funds origination transfers.	
100 Fedwire Funds receipt transfers.	
Fedwire monthly participation fee.	
2,000 FedACH origination items.	
FedACH monthly minimum fee—Forward Origination.	
25,000 FedACH receipt items.	
FedACH monthly minimum fee—Receipt.	
20 FedACH web-originated return/NOC.	
750 FedACH addenda record originated.	
1,500 FedACH addenda record received.	
200 FedACH SameDay Service—Forward Item Originated.	
FedACH Participation Fee.	
FedACH settlement fee.	
FedACH SameDay Service origination participation fee.	
FedComplete 200A Premier	**$1,500.00**.
includes:	
FedLine Advantage Premier package.	
Volumes included in the FedComplete 200A Plus package.	
FedComplete Excess Volume and Receipt Surcharge: [117]	
FedForward [118]	$0.03700/item.
FedReturn	$0.82000/item.
FedReceipt	$0.00005/item.
Fedwire Funds Origination	$0.88000/item.
Fedwire Funds Receipt	$0.08800/item.
FedACH Origination	$0.00350/item.
FedACH Receipt	$0.00035/item.
FedComplete credit adjustment	various.
FedComplete debit adjustment	various.
FedLine Solutions (monthly)	
FedMail [119]	$85.00.
includes:	

FEDLINE 2023 FEE SCHEDULE—Continued

[Effective January 3, 2023. **Bold indicates changes from 2022 prices.**]

	Fee
FedMail access channel. Check FedFoward, Fed Return and FedReceipt Services. Check Adjustments. FedACH Download Advice and Settlement Information. Fedwire Funds Offline Advices. Daily Statement of Account (Text). Monthly Statement of Service Charges (Text). Electronic Cash Difference Advices.	
FedLine Exchange [119]	$40.00.
includes: E-Payments Directory (via manual download).	
FedLine Exchange Premier [119] [120]	$125.00.
includes: FedLine Exchange package. E-Payments Directory (via automated download).	
FedLine Web [121]	$110.00.
includes: FedLine Web access channel. Services included in the FedLine Exchange package. Check FedForward, FedReturn and FedReceipt Services. Check Adjustments. FedACH Derived Returns and NOCs. FedACH File, Batch and Item Detail Information. FedACH Download Advice. FedACH Settlement Information. FedACH Customer Profile Information. FedACH Returns Activity Statistics. FedACH Risk RDFI Alert Service. FedACH Risk Returns Reporting Service. FedACH Exception Resolution Service. FedCash® Services.	
FedLine Web Plus [121]	$160.00.
includes: Services included in the FedLine Web package. FedACH Risk Origination Monitoring Service. FedACH FedPayments Reporter Service. Check Large Dollar Return. Check FedImage Services. Account Management Information (AMI). Daily Statement of Account (PDF, Text). Daylight Overdraft Reports. Monthly Account Services (SCRD) File. Monthly Statement of Service Charges (PDF, Text). E-Payments Routing Directory (via automated download).	
FedLine Advantage [121]	$415.00.
includes: FedLine Advantage access channel. One VPN device. Services included in the FedLine Web package. FedACH File Transmission To/From Federal Reserve. FedACH Request Output File Delivery. FedACH View File Transmission and Processing Status. Fedwire Originate and Receive Funds Transfer. Fedwire Originate and Receive Securities Transfer. National Settlement Service Services. Check Large Dollar Return. Check FedImage Services. Account Management Information with Intra-Day Download Search File. Daily Statement of Account (PDF, Text). Daylight Overdraft Reports. Monthly Account Services (SCRD) File. Monthly Statement of Service Charges (PDF, Text).	
FedLine Advantage Plus [121]	$460.00.
includes: Services included in the FedLine Advantage package. One VPN device. FedACH Risk Origination Monitoring Service. FedACH FedPayments Reporter Service. Fedwire Funds FedPayments Manager Import/Export (less than or equal to 250 Fedwire transactions and one routing number per month).	

FEDLINE 2023 FEE SCHEDULE—Continued

[Effective January 3, 2023. **Bold indicates changes from 2022 prices.**]

	Fee
FedTransaction Analyzer® (less than 250 or equal to Fedwire transactions and one routing number per month).	
E-Payments Routing Directory (via automated download).	
FedLine Advantage Premier [121]	$570.00.
Includes:	
FedLine Advantage Plus package.	
Two VPN devices.	
Fedwire Funds FedPayments Manager Import/Export (more than 250 Fedwire transactions or more than one routing number in a given month).	
FedTransaction Analyzer (more than 250 Fedwire transactions or more than one routing number per month).	
FedLine Command Plus [122]	$1,035.00.
includes:	
FedLine Command access channel.	
Services included in the FedLine Advantage Plus package.	
One VPN device.	
Additional FedLine Command server certificates.	
Fedwire Statement Services.	
Fedwire Funds FedPayments Manager Import/Export (more than 250 Fedwire transactions or more than one routing number in a given month).	
FedTransaction Analyzer (more than 250 Fedwire transactions or more than one routing number in a given month).	
Intra-Day File with Transaction Details (up to six times daily).	
Statement of Account Spreadsheet File (SASF).	
Financial Institution Reconcilement Data (FIRD) File (machine readable).	
FedLine Direct Plus [123]	$5,500.00.
includes:	
FedLine Direct access channel.	
Services included in the FedLine Command Plus package.	
One VPN device.	
One 2 Mbps Dedicated WAN Connection.	
Additional FedLine Direct server certificates.	
Treasury Check Information System (TCIS).	
Dual Vendors.	
FedLine Direct Contingency Solution.	
FedLine Direct Premier [123]	$10,500.00.
includes:	
Services included in the FedLine Direct Plus package.	
Two 2 Mbps dedicated WAN Connections.	
One Network Diversity.	
Two VPN devices.	
A la carte options (monthly) [124]	
Electronic Access:	
FedMail—FedLine Exchange Subscribers—Pack of 5 [125]	$25.00.
FedLine Subscribers—Pack of 5 (access to Web and Advantage)	$100.00.
Additional VPNs [126] [127]	$100.00.
Additional 2 Mbps WAN connection [123]	$3,000.00.
WAN Connection Upgrade.	
10 Mbps [128]	$1,700.00.
30 Mbps [128]	$3,000.00.
50 Mbps [128]	$4,000.00.
100 Mbps [128]	$7,000.00.
200 Mbps [128]	$11,000.00.
FedLine International Setup (one-time fee)	$5,000.00.
FedLine Custom Implementation Fee (one-time fee) [129]	various.
Network Diversity	$2,500.00.
FedMail Fax [130]	$200.00.
FedMail Email (for customers with FedLine Web and above) [131]	$85.00.
VPN Device Modification (one-time fee)	$200.00.
VPN Device Missed Activation Appointment (one-time fee)	$175.00.
VPN Device Expedited Hardware Surcharge (one-time fee)	$100.00.
VPN Device Replacement or Move (one-time fee)	$300.00.
E-Payments Automated Download (1–5 Add'l Codes) [132]	$75.00.
E-Payments Automated Download (6–20 Add'l Codes) [132]	$150.00.
E-Payments Automated Download (21–50 Add'l Codes) [132]	$300.00.
E-Payments Automated Download (51–100 Add'l Codes) [132]	$500.00.
E-Payments Automated Download (101–250 Add'l Codes) [132]	$1,000.00.
E-Payments Automated Download (>250 Add'l Codes) [132]	$2,000.00.

FEDLINE 2023 FEE SCHEDULE

[Effective January 3, 2023. **Bold indicates changes from 2022 prices.**]

	Fee
Accounting Information Services (monthly):	
Cash Management System (CMS) Plus—Own report—up to 12 files with [133].	
no OSRTN, respondent/sub-account activity	$60.00.
less than 10 OSRTNs, respondents and/or sub-accounts	$125.00.
10–50 OSRTNs, respondents and/or sub-accounts	$250.00.
51–100 OSRTNs, respondents and/or sub-accounts	$500.00.
101–500 OSRTNs, respondents and/or sub-accounts	$750.00.
>500 OSRTNs, respondents and/or sub-accounts	$1,000.00.
End-of-Day Financial Institution Reconcilement Data (FIRD) File [134]	$150.00.
Statement of Account Spreadsheet File (SASF) [135]	$150.00.
Intra-day Download Search Results in Spreadsheet Format (with AMI) [136]	$150.00.
Other:	
Software Certification	$0.00 to $8,000.00.
Vendor Pass-Through Fee	various.
Electronic Access Credit Adjustment	various.
Electronic Access Debit Adjustment	various.

[55] Any ODFI incurring less than $50 for the following fees will be charged a variable amount to reach the minimum: Forward value and non-value item origination fees, and FedGlobal ACH origination surcharges.

[56] Any RDFI not originating forward value and non-value items and incurring less than $40 in receipt fees will be charged a variable amount to reach the minimum. Any RDFI that originates forward value and non-value items incurring less than $50 in forward value and nonvalue item origination fees will only be charged a variable amount to reach the minimum monthly origination fee.

[57] This surcharge is assessed on all forward items that qualify for sameday processing and settlement and is incremental to the standard origination item fee.

[58] The fee includes the item and addenda fees in addition to the conversion fee.

[59] The fee includes the item and addenda fees in addition to the conversion fee. Reserve Banks also assess a $45 fee for every government paper return/NOC they process.

[60] Origination volumes at these levels qualify for a waterfall discount which includes all FedACH origination items.

[61] Origination discounts based on monthly billed receipt volume apply only to those items received by FedACH receiving points and are available only to Premium Receivers.

[62] RDFIs receiving through FedACH less than 90 percent of their FedACH-originated items.

[63] This per-item discount is a reduction to the standard receipt fees listed in this fee schedule.

[64] Receipt volumes at these levels qualify for a waterfall discount which includes all FedACH receipt items.

[65] RDFIs receiving through FedACH at least 90 percent of their FedACH-originated items, but less than 90 percent of all of their ACH items originated through any operator.

[66] This per-item discount is a reduction to the standard receipt fees listed in this fee schedule.

[67] RDFIs receiving through FedACH at least 90 percent of all of their ACH items originated through any operator.

[68] This per-item discount is a reduction to the standard receipt fees listed in this fee schedule.

[69] Criteria may be set for both the Origination Monitoring Service and the RDFI Alert Service. Subscribers with no criteria set up will be assessed the $35 monthly package fee.

[70] Monthly commercial receipt volume is calculated based on combined volume of subscribed ABAs in an account family.

[71] Premier reports generated on demand are subject to the package/tiered fees plus a surcharge.

[72] The fee applies to RTNs that have received or originated FedACH transactions during a month. Institutions that receive only U.S. government transactions or that elect to use a private-sector operator exclusively are not assessed the fee.

[73] This surcharge is assessed to any RTN that originates at least one item meeting the criteria for same-day processing and settlement in a given month.

[74] The fee is applied to any RTN with activity during a month, including RTNs of institutions that elect to use a private-sector operator exclusively but also have items routed to or from customers that access the ACH network through FedACH. This fee does not apply to RTNs that use the Reserve Banks for only U.S. government transactions.

[75] RDFIs receiving through FedACH at least 90 percent of their FedACH-originated items, but less than 90 percent of all of their ACH items originated through any operator.

[76] RDFIs receiving through FedACH at least 90 percent of all of their ACH items originated through any operator.

[77] RDFIs receiving through FedACH less than 90 percent of their FedACH-originated items.

[78] RDFIs receiving through FedACH less than 90 percent of their FedACH-originated items.

[79] Fee will be assessed only when automated NOCs are generated.

[80] Limited services are offered in contingency situations.

[81] The fees and credits listed are collected from the ODFI and credited to Nacha (admin network) or to the RDFI (same-day entry and unauthorized entry) in accordance with the *ACH Rules.*

[82] The international fees and surcharges vary from country to country as these are negotiated with each international gateway operator.

[83] A single monthly fee based on total FedGlobal ACH Payments origination volume.

[84] This per-item surcharge is in addition to the standard domestic origination fees listed in this fee schedule.

[85] This per-item surcharge is in addition to the standard domestic receipt fees listed in this fee schedule.

[86] The monthly fee is rolled up to the parent DI level, such that a DI that opts into the FedACH Exception Resolution Service under two separate RTNs would pay a single monthly fee based on the total number of cases opened for their two RTNs combined.

[87] A financial institution may enroll in the Service as an Offline Service Participant by designating the Reserve Bank to access and use the functionality of the application on behalf of the Offline Participant.

[88] The incentive discounts apply to the volume that exceeds 60 percent of a customer's historic benchmark volume. Historic benchmark volume is based on a customer's average daily activity over the previous five calendar years. If a customer has fewer than five full calendar years of previous activity, its historic benchmark volume is based on its daily activity for as many full calendar years of data as are available. If a customer has less than one year of past activity, then the customer qualifies automatically for incentive discounts for the year. The applicable incentive discounts are as follows: $0.736 for transfers up to 14,000; $0.228 for transfers 14,001 to 90,000; and $0.144 for transfers over 90,000.

[89] This surcharge applies to originators of transfers that are processed by the Reserve Banks after 5:00 p.m. eastern time.

[90] This fee is charged to any Fedwire Funds participant that originates a transfer message via the FedPayments Manager (FPM) Funds tool and has the import/export processing option setting active at any point during the month.

[91] Payment Notification and End-of-Day Origination surcharges apply to each Fedwire funds transfer message.

[92] Provided on billing statement for informational purposes only.

[93] This charge is assessed to settlement arrangements that use the Fedwire Funds Service to affect the settlement of interbank obligations (as opposed to those that use the National Settlement Service). With respect to such special settlement arrangements, other charges may be assessed for each funds transfer into or out of the accounts used in connection with such arrangements.

[94] If your organization is a settlement agent, it may be able to use the National Settlement Service offline service if it is experiencing an operational event that prevents the transmission of settlement files via its electronic connection to the Federal Reserve Banks. The Federal Reserve Banks have limited capacity to process offline settlement files. As a result, while the Federal Reserve Banks use best efforts to process offline settlement file submissions, there is no guarantee that an offline settlement file, in particular one that is submitted late in the operating day or that contains a large

Continued

number of entries, will be accepted for processing. Only those persons identified as authorized individuals on the National Settlement Service 04 Agent Contact Form may submit offline settlement files. For questions related to the National Settlement Service offline service, please contact National Settlement Service Central Support Service Staff (CSSS) at 800–758–9403, or via email at *csss.staff@ny.frb.org.*

[95] Any settlement arrangement that accrues less than $60 during a calendar month will be assessed a variable amount to reach the minimum monthly fee.

[96] Restricted Securities Accounts maintained by the Reserve Banks under the Loans and Discounts program and the 31 CFR part 202 program are not assessed for monthly account maintenance fees or fees for Transfers of Book-Entry Securities to or from such Restricted Securities Accounts. Restricted Securities Accounts maintained by the Reserve Banks under the 31 CFR part 225 program are subject to monthly account maintenance fees but not fees for Transfers of Book-Entry Securities to or from such Restricted Securities Accounts.

[97] These fees are set by the Federal Reserve Banks.

[98] This surcharge is set by the Federal Reserve Banks. It is in addition to any basic transfer or reversal fee.

[99] Restricted Securities Accounts maintained by the Reserve Banks under the Loans and Discounts program and the 31 CFR. part 202 program are not assessed for monthly account maintenance fees or fees for Transfers of Book-Entry Securities to or from such Restricted Securities Accounts. Restricted Securities Accounts maintained by the Reserve Banks under the 31 CFR part 225 program are subject to monthly account maintenance fees but not fees for Transfers of Book-Entry Securities to or from such Restricted Securities Accounts.

[100] These fees are set by the Federal Reserve Banks.

[101] These fees are set by the Federal Reserve Banks.

[102] The U.S. Department of the Treasury absorbs the monthly account maintenance fees the Federal Reserve Banks charge to the extent a securities account contains only Treasury securities.

[103] The U.S. Department of the Treasury absorbs the monthly account maintenance fees the Federal Reserve Banks charge to the extent a securities account contains only Treasury securities.

[104] These fees are set by the Federal Reserve Banks.

[105] Automated Claim Adjustment Process (ACAP) fees apply to all ACAP-eligible security types. For information about ACAP's enhancements coming up in 2023 and their implementation dates, please visit this website.

[106] The billing code 20141, Fail Claim Adjustment Fee, will be sunset once Phase 1 of the ACAP's Enhancement Project goes live. For information about ACAP's enhancements implementation dates, please visit this website.

[107] The billing codes 20144, Fail Claim Adjustment Fee (Debit), and 20145, Fail Claim Adjustment Fee (Credit), will be introduced once Phase 1 of the ACAP's Enhancement Project goes live. These fees will replace the billing code 20141, Fail Claim Adjustment Fee. For information about ACAP's enhancements implementation dates, please visit this website.

[108] Participants are charged the Repo Position Maintenance Fee for both a Repo-Out balance and a Repo-In balance. These fees will be assessed every business day.

[109] Participants are charged the Securities Lending Position Maintenance Fee for both a Securities Borrowed balance and a Securities Lent balance. These fees will be assessed every business day.

[110] This fee is set by and remitted to the Government National Mortgage Association (GNMA).

[111] The Federal Reserve Banks charge participants a Joint Custody Origination Surcharge for both Agency and Treasury securities.

[112] These fees are set by the Federal Reserve Banks.

[113] These fees are set by the Federal Reserve Banks.

[114] FedComplete packages are all-electronic service options that bundle payment services with an access solution for one monthly fee.

[115] FedComplete customers that use the email service would be charged the FedMail Email a la carte fee and for all FedMail-FedLine Exchange Subscriber 5-packs.

[116] Packages with an ''A'' include the FedLine Advantage channel.

[117] Per-item surcharges are in addition to the standard fees listed in the applicable priced services fee schedules.

[118] FedComplete customers will be charged $4 for each FedForward cash letter over the monthly package threshold. This activity will appear under billing code 51998 in Service Area 1521 on a month-lagged basis.

[119] FedMail and FedLine Exchange packages do not include user credentials, which are required to access priced services and certain informational services. Credentials are sold separately in packs of five via the FedMail-FedLine Exchange Subscriber 5-pack.

[120] Additional VPNs are available for FedLine Advantage, FedLine Command, and FedLine Direct packages only. All customers will need to replace their existing VPN device with the new VPN device. Effective October 1, 2023, customers who have not started migration will be assessed a $400 monthly fee until migration is complete.

[121] FedLine Web and Advantage packages do not include user credentials, which are required to access priced services and certain informational services. Credentials are sold separately in packs of five via the FedLine Subscriber 5-pack.

[122] FedLine Solutions package fees associated with establishing a new connection or upgrading a current connection to FedLine Advantage®, FedLine Command®, or FedLine Direct® for the FedNowSM Service will be credited back on a monthly basis in 2023.

[123] Early termination fees and/or expedited order fees may apply to all FedLine Direct packages and FedLine Direct a la carte options.

[124] These add-on services can be purchased only with a FedLine Solution.

[125] New FedNow℠ Subscribers will not contribute toward the FedLine Subscribers—Pack of 5 monthly fee in 2023.

[126] Additional VPNs are available for FedLine Advantage, FedLine Command, and FedLine Direct packages only. All customers will need to replace their existing VPN device with the new VPN device. Effective October 1, 2023, customers who have not started migration will be assessed a $400 monthly fee until migration is complete.

[127] An additional VPN or WAN device leveraged exclusively for the FedNow℠ Service will not be assessed the monthly ala carte fee for the device(s) in 2023. While customers may opt to add a WAN router of any applicable line speed for the FedNow℠ Service, the total monthly qualifying amount will be limited to $5,000 per month.

[128] Fee is in addition to the FedLine Direct package fees or additional 2Mbps WAN fees.

[129] The FedLine Custom Implementation Fee is $2,500 or $5,000 based on the complexity of the setup.

[130] Limited to installed base only. All customers will need to migrate FedMail Fax services to FedMail or FedLine services, where applicable. Effective October 1, 2023, the price will increase to $400 for FedMail Fax.

[131] Available only to customers with a priced FedLine package.

[132] Five download codes are included at no cost in all Plus and Premier packages.

[133] Cash Management Service options are limited to Plus and Premier packages.

[134] The End of Day Financial Institution Reconcilement Data (FIRD) File option is available for FedLine Web Plus, FedLine Advantage Plus and Premier packages. It is available for no extra fee in FedLine Command Plus and Direct packages.

[135] The Statement of Account Spreadsheet File (SASF) option is available for FedLine Web Plus, FedLine Advantage Plus and Premier packages. It is available for no extra fee in FedLine Command Plus and Direct packages.

[136] The Intra-day Download Search Results in Spreadsheet Form option is available for the FedLine Web Plus package. It is available for no extra fee in FedLine Advantage and higher packages.

By order of the Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2022–28096 Filed 12–23–22; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than January 11, 2023.

A. Federal Reserve Bank of Kansas City

(Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198.

1. *Roger D. Cattle, Lincoln, Nebraska, and John T. Cattle, Overland Park, Kansas, as co-voting proxies of the John W. Cattle, Jr. Bank Stock Marital Trust, Seward, Nebraska;* to become members of the Cattle Family Group, a group acting in concert, to retain voting shares of Cattle Crossing, Inc., and thereby indirectly retain voting shares of Cattle Bank and Trust Company, both of Seward, Nebraska.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–28122 Filed 12–23–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1796]

Modifications to the Federal Reserve Policy on Payment System Risk To Accommodate Enhancement to the Automated Claim Adjustment Process

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is revising part II of the Federal Reserve Policy on Payment System Risk (PSR policy) to add a posting rule to facilitate the implementation of enhancements to the Automated Claim Adjustment Process (ACAP).

DATES: *Applicability Date:* January 30, 2023.

FOR FURTHER INFORMATION CONTACT: Jason A. Hinkle, Deputy Associate Director (202–912–7805) or Benjamin J. Hobbs, Senior Financial Institution Policy Analyst (202–872–7549), Division of Reserve Bank Operations and Payment Systems. Cody Gaffney (202–452–2633), Senior Attorney, Legal Division, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, Washington, DC 20551. For users of TTY–TRS, please call 711 from any telephone, anywhere in the United States.

SUPPLEMENTARY INFORMATION:

I. Background

Part II of the PSR policy governs the provision of intraday credit (also known as daylight overdrafts) in accounts at the Reserve Banks.[1] The PSR policy includes procedures, referred to as posting rules, that are used to measure account balances. The posting rules establish settlement times for debits and credits at Federal Reserve accounts for different payment types.

The ACAP is a feature of the Fedwire® Securities Service (''Fedwire Securities'' or ''Service'') that offers Fedwire Securities participants (participants) the option to automate principal and interest (P&I) tracking and claim adjustments related to transactions between participants that settle over Fedwire Securities.[2] The Reserve Banks, in their capacity as fiscal agents for issuers of securities issued over Fedwire Securities, make P&I payments to record-date holders of the securities.[3] For some types of transactions between participants, such as repurchase agreements (repos), the participant identified as the record-date holder by the Service may not be entitled to the P&I payment pursuant to a separate agreement between the transaction participants. The ACAP offers an automated way for the record-date holder to transfer a P&I payment from its master account to the master account of the designated participant.

In January 2022 the Federal Reserve Banks announced phased enhancements to the Service that will expand ACAP tracking to all coupon-paying securities issued over Fedwire Securities, add securities lending as a transaction type, and shift the timing of settling claim adjustments.[4] Currently, ACAP adjustments are settled at approximately 4:30 p.m. ET via the National Settlement Service (NSS). Most, but not all claim adjustments are associated with that day's P&I payment which are generally made earlier in the day. The shift in the timing of settling claim adjustments is designed to narrow the timing gap between P&I payments and the associated claim adjustments. To effect this shift in timing, the ACAP enhancements include a design change to utilize new Fedwire Securities messages to settle claims, which result in claim adjustments being effected promptly after the associated P&I payments are made. This design change will be implemented January 30, 2023.

II. New Posting Rule To Accommodate the ACAP Enhancements

Currently, ACAP adjustments are not explicitly mentioned in the posting rules of the PSR policy because ACAP adjustments are settled using NSS, which has its own posting rule.[5] The Board is adding a new posting rule to part II of the PSR policy to reflect the fact that ACAP adjustments will be made on a gross basis through Fedwire Securities throughout the business day.

The ACAP enhancements and the new posting rule are not expected to increase risk to the Reserve Banks or the payment system, even as the ACAP expands to additional security and transaction claim types and as claim adjustment volume increases. ACAP debit adjustments are small compared to the participants' aggregate P&I credits on a given day and analysis shows that they are not expected to significantly impact participants' master account balances. In addition, all participants will be notified of all claim adjustments before the adjustments are processed.

III. Technical Changes to Text of the PSR Policy

In addition to the new posting rule to accommodate the ACAP enhancements, the Board is modifying footnote 37 of the PSR policy by adding a hyperlink to a frequently updated document containing a list of securities issuers, including GSEs, rather than listing the securities issuers directly in the footnote. This change is not substantive in nature and reflects current practices that the Reserve Banks use to administer the PSR policy.

IV. Federal Reserve Policy on Payment System Risk

[The following portion titled ''Federal Reserve Policy on Payment System Risk'' will not publish in the Code of Federal Regulations.]

Federal Reserve Policy on Payment System Risk

Part II. Federal Reserve Intraday Credit Policies

Under ''Procedures for Measuring Daylight Overdrafts'', revise ''Opening balance (previous day's closing

[1] The Board's PSR policy is available at: *https://www.federalreserve.gov/paymentsystems/psr_about.htm.*

[2] An ACAP claim adjustment is a transfer of funds from one Fedwire Securities participant to another participant over the Service.

[3] Issuers provide securities record dates and payment dates information to the Fedwire Securities Service. As an operational matter, a participant who is identified by the Service as the holder of a security after the Service closes on the business day prior to the security's record date is a record-date holder of the security. A record-date holder of a security is entitled to payment of P&I on that security, and the P&I payment is distributed to record-date holders on the payment date associated with the record date regardless of whether the participant still holds the security on the payment date.

[4] *See FRBServices.org, New Implementation Plan for the Automated Claim Adjustment Process Enhancements* (Jan. 18, 2022), *https://www.frbservices.org/news/communications/011822-fedwire-securities-participants-service-providers.* For the most recent information regarding the ACAP enhancements, *see https://www.frbservices.org/resources/financial-services/securities/acap.*

[5] NSS entries settle throughout the business day as the Reserve Banks process NSS files.

balance)'', ''Post throughout business day'' as follows:

A. Daylight overdraft definition and measurement

* * * * *

Procedures for measuring daylight overdrafts [34]

Opening balance (previous business day's closing balance)

Post throughout the business day:

+/- FedNow funds transfers
+/- Fedwire funds transfers [35]
+/- Fedwire book-entry securities transfers
+/- Fedwire book-entry automated claim adjustments [36]
+/- National Settlement Service entries.
+ Fedwire book-entry interest and redemption payments on securities that are not obligations of, or fully guaranteed as to principal and interest by, the United States [37]
+ Electronic payments for matured coupons and definitive securities that are not obligations of, or fully guaranteed as to principal and interest by, the United States. [38]

The term ''interest and redemption payments'' refers to payments of principal, interest, and redemption on securities maintained on the Fedwire Securities Service.

The Reserve Banks will post these transactions, as directed by the issuer, provided that the issuer's Federal Reserve account contains funds equal to or in excess of the amount of the interest and redemption payments to be made. In the normal course, if a Reserve Bank does not receive funding from an issuer for the issuer's interest and redemption payments by the established cut-off hour of 4:00 p.m. eastern time on the Fedwire Securities Service, the issuer's payments will not be processed on that day.

* * * * *

[34] This schedule of posting rules does not affect the overdraft restrictions and overdraft measurement provisions for nonbanks established by the Competitive Equality Banking Act of 1987 and the Board's Regulation Y (12 CFR 225.52).

[35] Funds transfers that the Reserve Banks function for certain international organizations using internal systems other than payment processing systems such as Fedwire will be posted throughout the business day for purposes of measuring daylight overdrafts.

[36] Claim adjustments are debits and credits associated with the Fedwire Securities Service's Automated Claim Adjustment Process (ACAP).

[37] For a complete list of securities issuers, including GSEs, please visit *https://www.frbservices.org/resources/financial-services/securities/user-guide.html.*

[38] Electronic payments for credits on these securities will post according to the posting rules for the mechanism through which they are processed, as outlined in this policy. However, the majority of these payments are made by check and will be posted according to the established check posting rules as set forth in this policy.

By order of the Board of Governors of the Federal Reserve System, acting through the Director of the Division of Reserve Bank Operations and Payment Systems under delegated authority.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2022–28095 Filed 12–23–22; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 26, 2023.

A. Federal Reserve Bank of Dallas (Karen Smith, Director, Applications) 2200 North Pearl St., Dallas, Texas 75201:

1. *Vista Bancshares, Inc., Dallas, Texas;* to acquire Charis Holdings, Inc., Dallas, Texas, and thereby, indirectly acquire Charis Bank, Justin, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2022–28127 Filed 12–23–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10510]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by January 26, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title:* Basic Health Program (BHP) Supporting Regulations; *Use:* In accordance with Section 1331 of the Patient Protection and Affordability Care Act, Public Law 111–148 (ACA), BHP is federally funded by determining the amount of payments that the federal government would have made through premium tax credits and cost-sharing reductions for people enrolled in BHP had they instead been enrolled in an Exchange. States must submit a BHP Blueprint to CMS for certification prior to the state implementing a BHP and must submit a revised Blueprint in the event that a state seeks to make significant changes that alter program operations; the BHP benefit package; or enrollment, disenrollment, and verification policies described in the Blueprint. Such States must also submit a BHP annual report. In addition to the reinstatement, this 2022 iteration proposes changes that are associated with the March 12, 2014 (79 FR 14112) BHP final rule that have not previously received PRA approval. *Form Number:* CMS–10510 (OMB control number: 0938–1218); *Frequency:* Monthly and annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 2*; Number of Responses:* 27; *Total Annual Hours:* 2,568. For policy questions regarding this collection contact Cassie Lagorio at 443–721–8022.

Dated: December 21, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–28105 Filed 12–23–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0218]

Submission for Office of Management and Budget Review; Tribal Child Support Enforcement Direct Funding Request

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF) is requesting a 3-year extension of the Tribal Child Support Enforcement Direct Funding Requests-45 CFR 309 (Office of Management and Budget (OMB)) #0970–0218, expiration March 31, 2023) with revisions. We are proposing to provide an optional Table of Contents and Cover Sheet for plan pages.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *ocse.tribal@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The final rule within 45 CFR part 309, published in the **Federal Register** on March 30, 2004, contains a regulatory reporting requirement that, in order to receive funding for a Tribal IV–D program, a tribe or tribal organization must submit a plan describing how the tribe or tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity; establishing, modifying, and enforcing support orders; and locating noncustodial parents. The plan is required for all tribes requesting funding; however, once a tribe has met the requirements to operate a comprehensive program, a new plan is not required annually unless a tribe makes changes to its title IV–D program. If a tribe or tribal organization intends to make any substantial or material changes, a Tribal IV–D plan amendment must be submitted for approval. Tribes and tribal organizations must have an approved plan and submit any required plan amendments in order to receive funding to operate a Tribal IV–D program. With this request to extend approval of this information collection, OCSE is proposing a change to the paperwork collection by providing optional plan pages. The optional plan pages organize the Tribal IV–D plan, identify required attachments, and streamline plan amendment submissions. Tribes and tribal organizations who choose to participate will attest to complying with the regulatory requirements in 45 CFR, Parts 309 and 310 and submit plan amendments for changes to the required attachments identified in the Table of Contents. The optional plan pages organize the Tribal IV–D plan, identify required attachments, and streamline plan amendment submissions.

Respondents: Tribes and tribal Organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
45 CFR 309–New Plan	2	1	480	960

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
45 CFR 309–Plan Amendment	60	1	105	6300

Estimated Total Annual Burden Hours: 7,260.

Authority: Title IV–D of the Social Security Act; 45 CFR 309.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–28053 Filed 12–23–22; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Child Welfare Study To Enhance Equity With Data (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) within the Administration for Children and Families (ACF) is proposing a new information collection for the Child Welfare Study to Enhance Equity with Data (CW–SEED). The project aims to understand how and to what extent data are used to explore equity in service delivery and child and family outcomes, to identify barriers or problematic data practices, and to explore efforts by child welfare agencies and their partners to use data to reduce barriers across the continuum of child welfare services.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: CW–SEED will conduct qualitative case studies to describe the experiences of up to six state, local, and/or tribal child welfare agencies and their partners collecting and using data to advance equity in service delivery and child and family outcomes. The case studies will document promising data practices and the potential challenges to implementing them. Each case study will include two components (1) collection and review of site-specific documents and other relevant information, and (2) in-person site visits to collect detailed qualitative data and any additional documentation the sites can provide. This information collection aims to present an internally valid description of the experiences of the sites, not to promote statistical generalization to different sites.

Respondents: Child welfare agency leaders, managers or supervisors of direct service workers, direct service workers, and staff who work with the agency's data systems and/or conduct research; partner agency and community organization leaders, managers or supervisors of direct service workers, direct service workers, and staff who work with the organization's data systems and/or conduct research; and, members of advisory groups that work with child welfare agencies, partner agencies, or community organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Instrument 1: Interview topic guide	180	1	2	360	180
Instrument 2: Child welfare agency advisory focus group guide	42	1	1.5	63	32
Instrument 3: Partner agency and community organization advisory focus group guide	18	1	1.5	27	14
Instrument 4: Demonstration guide	12	1	1	12	6

Estimated Total Annual Burden Hours: 232.

Authority: Social Security Act 426 [42 U.S.C. 626]

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–28068 Filed 12–23–22; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The purpose of the IACC meeting is to discuss business, agency updates, and issues related to autism spectrum disorder (ASD) research and services activities. The meeting will be open to the public for viewing virtually via NIH Videocast. Individuals who plan to view the meeting virtually and need special assistance or other reasonable accommodations to view the meeting should notify the Contact Person listed below at least seven (7) business days in advance of the meeting. The open session can be accessed from the NIH Videocast website (*http://videocast.nih.gov/*).

Name of Committee: Interagency Autism Coordinating Committee.

Date: January 18, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Meeting Access: https://videocast.nih.gov/watch=48611.

Agenda: To discuss business, updates, and issues related to ASD research and services activities.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (*www.iacc.hhs.gov*) prior to the meeting. Pre-registration is recommended.

Deadlines:

Written/Virtual Public Comment Due Date: Tuesday, January 10, 2023, by 5:00 p.m. ET Public Comment Guidelines.

For public comment instructions, see below.

Contact Person: Ms. Rebecca Martin, Office of Autism Research Coordination, National Institute of Mental Health, NIH, Phone: 301–435–0886, Email: *IACCPublicInquiries@mail.nih.gov.*

Public Comments: The IACC welcomes written and virtual public comments from members of the autism community and asks the community to review and adhere to its Public Comment Guidelines.

In the 2016–2017 IACC Strategic Plan, the IACC listed the ''Spirit of Collaboration'' as one of its core values, stating that, ''We will treat others with respect, listen with open minds to the diverse views of people on the autism spectrum and their families, thoughtfully consider community input, and foster discussions where participants can comfortably offer opposing opinions.'' In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also adhere to this core value.

A limited number of slots are available for individuals to provide a ~3-minute summary or excerpt of their written comment via the virtual platform to the Committee during the meeting. For those interested in that opportunity, please indicate ''Interested in providing virtual oral comment'' in your written submission, along with your name, address, email, phone number, and professional/organizational affiliation so that OARC staff can contact you if a slot is available for you to provide a summary or excerpt of your comment via the virtual platform during the meeting.

For any given meeting, priority for live virtual comment slots will be given to individuals who have not previously provided live virtual comments in the current calendar year. This will help ensure that as many individuals as possible have an opportunity to share comments. Commenters going over their allotted 3-minute slot may be asked to conclude immediately in order to allow other comments and the rest of the meeting to proceed on schedule.

Public comment submissions received by 5:00 p.m. ET on Tuesday, January 10, 2023, will be provided to the Committee prior to the meeting for their consideration. Any written comments received after 5:00 p.m. ET, Tuesday, January 10, 2023, may be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. The Committee is not able to respond individually to comments. All public comments become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided. For public comment guidelines, see: *https://iacc.hhs.gov/meetings/public-comments/guidelines/.*

Technical issues: If you experience any technical problems with the webcast, please email *IACCPublicInquiries@mail.nih.gov.*

Disability Accommodations: All IACC Full Committee Meetings provide Closed Captioning through the NIH videocast website. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language or interpreting services, etc.) must submit a request to the Contact Person listed on the notice at least seven (7) business days prior to the meeting. Such requests should include a detailed description of the accommodation needed and a way for the IACC to contact the requester if more information is needed to fill the request. Special requests should be made at least seven (7) business days prior to the meeting; last-minute requests may be made but may not be possible to accommodate.

Additional Information: Information about the IACC is available on the website: *http://www.iacc.hhs.gov.*

Dated: December 21, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–28133 Filed 12–23–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health 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 Institute of Environmental Health Sciences Special Emphasis Panel; Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences (R21).

Date: January 19, 2023.

Time: 10:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, Keystone Building, 530 Davis Driv,e Durham, NC 27709 (Virtual Meeting).

Contact Person: Qingdi Quentin Li, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, (240) 858–3914, *liquenti@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: December 20, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–28108 Filed 12–23–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

The meeting will be open to the public. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: January 30, 2023.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: Report of Division Director and Division Staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 8D49, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Pamela Gilden, Branch Chief, Science Planning and Operations Branch, Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 8D49, Rockville, MD 20852–9831, 301–594–9954, *pamela.gilden@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 10 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 20, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–28107 Filed 12–23–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0022]

Technical Mapping Advisory Council; Meeting

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Federal Emergency Management Agency (FEMA) Technical Mapping Advisory Council (TMAC) will hold an in-person public meeting with a virtual option on Monday, January 23, 2023, and Tuesday, January 24, 2023. The meeting will be open to the public in-person and via a Microsoft Teams Video Communications link.

DATES: The TMAC will meet on Monday, January 23, 2023, and Tuesday, January 24, 2023, from 8:00 a.m. to 5:00 p.m. Eastern Time (ET). Please note that the meeting will close early if the TMAC has completed its business.

ADDRESSES: The meeting will be held in-person at Michael Baker International, 3601 Eisenhower Ave. Ste. 600, Alexandria, VA 22304, and virtually using the following Microsoft Teams Video Communications link (Monday Link: *https://bit.ly/3FdGFXa;* Tuesday Link: *https://bit.ly/3VzEUbR*). Members of the public who wish to attend the in-person or virtual meeting must register in advance by sending an email to *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper) by 5:00 p.m. ET on Thursday, January 19, 2023. For information on services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** caption below as soon as possible.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the TMAC, as listed in the **SUPPLEMENTARY INFORMATION** caption below. Associated meeting materials will be available upon request after Tuesday, January 17, 2023. The draft 2022 TMAC Annual Report Outline will be available for review after Tuesday, January 17, 2023. To receive a copy of any relevant materials, please send the request to: *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper). Written comments to be considered by the committee at the time of the meeting must be submitted and received by Wednesday, January 18, 2023, 5:00 p.m. ET identified by Docket ID FEMA–2014–0022, and submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address the email to: *FEMA-TMAC@fema.dhs.gov.* Include the docket number in the subject line of the message. Include name and contact information in the body of the email.
- *Instructions:* All submissions received must include the words ''Federal Emergency Management Agency'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may wish to review the Privacy & Security Notice via a link on the homepage of *www.regulations.gov.*
- *Docket:* For docket access to read background documents or comments received by the TMAC, go to *http://www.regulations.gov* and search for the Docket ID FEMA–2014–0022.

A public comment period will be held on Monday, January 23, 2023, from 3:30 p.m. to 4:00 p.m. ET and Tuesday, January 24, 2023, from 11:45 a.m. to 12:15 p.m. ET. The public comment period will not exceed 30 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker by Wednesday, January 18, 2023, 5:00 p.m. ET. Please be prepared to submit a written version of your public comment.

FEMA is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** caption as soon as possible.

FOR FURTHER INFORMATION CONTACT: Brian Koper, Designated Federal Officer for the TMAC, FEMA, 400 C Street SW, Washington, DC 20024, telephone 202–646–3085, and email *brian.koper@fema.dhs.gov.* The TMAC website is: *https://www.fema.gov/flood-maps/guidance-partners/technical-mapping-advisory-council*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. App.

In accordance with the *Biggert-Waters Flood Insurance Reform Act of 2012,* the TMAC makes recommendations to the FEMA Administrator on: (1) how to improve, in a cost-effective manner, the (a) accuracy, general quality, ease of use,

and distribution and dissemination of flood insurance rate maps and risk data; and (b) performance metrics and milestones required to effectively and efficiently map flood risk areas in the United States; (2) mapping standards and guidelines for (a) flood insurance rate maps, and (b) data accuracy, data quality, data currency, and data eligibility; (3) how to maintain, on an ongoing basis, flood insurance rate maps and flood risk identification; (4) procedures for delegating mapping activities to State and local mapping partners; and (5) (a) methods for improving interagency and intergovernmental coordination on flood mapping and flood risk determination, and (b) a funding strategy to leverage and coordinate budgets and expenditures across Federal agencies. Furthermore, the TMAC is required to submit an annual report to the FEMA Administrator that contains: (1) a description of the activities of the Council; (2) an evaluation of the status and performance of flood insurance rate maps and mapping activities to revise and update Flood Insurance Rate Maps; and (3) a summary of recommendations made by the Council to the FEMA Administrator.

Agenda: The purpose of this meeting is for the TMAC members to discuss and vote on the content of the 2023 TMAC Annual Report Outline. Any related materials will be available upon request prior to the meeting to provide the public an opportunity to review the materials. The full agenda and related meeting materials will be available upon request by Tuesday, January 17, 2023. To receive a copy of any relevant materials, please send the request to: *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper).

Michael M. Grimm,

Assistant Administrator for Risk Management, Federal Emergency Management Agency.

[FR Doc. 2022–28140 Filed 12–23–22; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2022–0018]

Request To Revise and Extend the Chemical Security Assessment Tool (CSAT) Information Collection Under the Paperwork Reduction Act

AGENCY: Cybersecurity and Infrastructure Security Agency, DHS.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Infrastructure Security Division (ISD) within the Cybersecurity and Infrastructure Security Agency (CISA) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. This notice solicits comments on the information collection during a 60-day public comment period prior to the submission of this ICR to OMB. The submission proposes to revise the information collection for an additional three years and update the burden estimates associated with collecting information in the Chemical Security Assessment Tool (CSAT) for the Chemical Facility Anti-Terrorism Standards (CFATS) Program.

DATES: Comments are due by February 27, 2023.

ADDRESSES: You may send comments, identified by docket number through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for sending comments.

Instructions: All submissions received must include the agency name ''CISA'' and docket number CISA–2022–0018. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Comments that include protected information such as trade secrets, confidential commercial or financial information, Chemical-terrorism Vulnerability Information (CVI),[1] Sensitive Security Information (SSI),[2] or Protected Critical Infrastructure Information (PCII) [3] should not be submitted to the public docket. Comments containing protected information should be appropriately marked and packaged in accordance with all applicable requirements and submission must be coordinated with the point of contact for this notice provided in **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ryan Donaghy, 703–603–5000, *CISARegulations@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The CFATS Program identifies chemical facilities of interest and regulates the security of high-risk chemical facilities through a risk-based approach. The CFATS Program is authorized under the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014 or ''CFATS Act of 2014.[4]

CISA collects the core regulatory data necessary to implement CFATS through the Chemical Security Assessment Tool (CSAT) covered under this collection. For more information about CFATS and CSAT, please visit *www.dhs.gov/chemicalsecurity.* This information collection (OMB Control No. 1670–0007) will expire on July 31, 2023.[5]

Below, CISA estimates the burden to respondents for the: (1) Top-Screen, (2) Security Vulnerability Assessment (SVA) and Alternative Security Program (ASP) submitted in lieu of an SVA, (3) Site Security Plan (SSP) and ASP submitted in lieu of an SSP, (4) CFATS Help Desk, (5) CSAT User Registration, and (6) Identification of Facilities and Assets at Risk.[6]

1. CISA'S Methodology in Estimating the Burden for the Top–Screen

Number of Respondents: The current information collection estimated that 2,332 respondents will submit a Top-Screen annually. For this ICR, CISA estimates the annual number of respondents will be 3,817.

The estimate of 3,817 is the sum of the average number of 887 first-time Top-Screen submissions and the average number of 2,930 Top-Screen resubmissions received per year between Calendar Year (calendar year)19 and CY21 (887 first time submissions + 2,930 resubmissions = 3,817).

Estimated Time per Respondent: In the current information collection, the estimated time per respondent to prepare and submit a Top-Screen is 1.09 hours. For this ICR, CISA estimates the time per respondent to prepare and submit a Top-Screen will be 2.04 hours.

Using the data collected between CY19 and CY21, CISA obtained the estimate of 2.04 hours by first determining the average amount of time respondents were logged into the Top-Screen application (0.408 hours or 24.5 minutes). CISA calculated this figure by

[1] For more information about CVI see 6 CFR 27.400 and the CVI Procedural Manual at *www.dhs.gov/publication/safeguarding-cvi-manual.*

[2] For more information about SSI see 49 CFR part 1520 and the SSI Program web page at *www.tsa.gov/for-industry/sensitive-security-information.*

[3] For more information about PCII see 6 CFR part 29 and the PCII Program web page at *www.dhs.gov/pcii-program.*

[4] The CFATS Act of 2014 codified the CFATS program into the Homeland Security Act of 2002. See 6 U.S.C. 621 *et seq.,* as amended by Public Law 116–135, Sec. 16007 (2020).

[5] The currently approved version of this information collection (OMB Control No. 1670–0007) can be viewed at*https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201905-1670-001.*

[6] Throughout this analysis, CISA presents rounded hourly time burden estimates and hourly compensation rates to assist in reproducing the results. However, CISA's actual calculations use unrounded figures; consequently, some reproduced results may not exactly match the reported results.

using the time logged in the application for initial Top-Screens (.50 hours) and Top-Screen resubmission (.38 hours) weighted by the number of respondents that submitted first-time Top-Screens and Top-Screen resubmissions [(887 first-time submissions × 0.50 hours per first time submission) + (2,930 resubmissions × 0.38 hours per resubmission) ÷ 3,817 total submissions = 0.408 hours].

CISA maintains its assumption, based on previous public comments on this information collection, that for every hour a respondent is logged into the Top-Screen application, the respondent spends an average of 4 hours in preparation.[7] Therefore, based on the 0.408 hours average log in time for the Top-Screen application and the 4 hours of average preparation time, CISA calculates that between CY19 and CY21, the burden per respondent to submit a Top-Screen was 2.04 hours [0.408 hours logged into CSAT + (0.408 hours × 4) for preparation = 2.04 hours].

Annual Burden Hours: The annual burden hours for the Top-Screen is 7,785 hours (3,817 respondents × 1 response per respondent × 2.04 hours per response = 7,785 hours).

Total Annual Burden Cost: CISA assumes that Site Security Officers (SSOs) are responsible for submitting Top-Screens. For this ICR, CISA maintains this assumption.

To estimate the total annual burden, CISA multiplied the annual burden of 7,785 hours by the average hourly total compensation rate of SSOs of $90.41[8] per hour. Therefore, the total annual burden cost for the Top-Screen is $703,829 (*i.e.,* 7,785 hours multiplied by $90.41 per hour).

Total Burden Cost (Capital/Startup): CISA provides access to CSAT free of charge and CISA assumes that each respondent already has access to the internet for basic business needs. Therefore, CISA estimates that no capital/startup costs are associated with this instrument.

Total Recordkeeping Burden A respondent that has submitted a Top-Screen may or may not be determined by CISA to present a high level of security risk. Only respondents that present a high level of security risk are required to keep records mandated by CFATS (*i.e.,* facilities that tier into the CFATS program).

For respondents that are determined to present a high level of security risk, the Top-Screen recordkeeping burden is accounted for within the recordkeeping burden estimate for the ''Site Security Plan (SSP) and Alternative Security Program (ASP) submitted in lieu of an SSP'' instrument discussed later in this notice in subsection 3, hereafter, referred to as the ''SSP/ASP.'' The recordkeeping burden estimate for the SSP/ASP instrument accounts for all records respondents are required to maintain under CFATS because CISA assumes that respondents maintain their Top-Screen records in the same manners, formats, and locations as they maintain their other required records. Therefore, CISA estimates that no recordkeeping burden is associated with this instrument.

2. CISA'S Methodology in Estimating the Burden for the Security Vulnerability Assessment (SVA) & Alternative Security Program (ASP) Submitted in Lieu of an SVA

Number of Respondents: The current information collection estimated that each year 1,683 respondents would complete an SVA or ASP in lieu of an SVA, hereafter, referred to as an ''SVA/ASP.'' For this ICR, CISA estimates that the annual number of respondents will be 2,328, which is based on sum of the average number of SVA/ASP submissions and resubmissions between CY19 and CY21. This consists of an average of 209 first-time SVA/ASPs and 2,119 resubmitted SVA/ASPs per year.

Estimated Time per Respondent: The current information collection estimated the time per respondent for preparing and submitting an SVA/ASP to be 1.24 hours. For this ICR, CISA estimates the time per respondent for preparing and submitting an SVA/ASP will be 1.4136 hours.

Using the data collected between CY19 and CY 21, CISA obtained the estimate of 1.4136 hours by first determining the median amount of time respondents were logged into the SVA/ASP application (0.28 hours or 17 minutes). CISA calculated the average amount of time respondents were logged into the SVA/ASP application by using the median duration respondents were logged into the CSAT SVA/ASP application for an initial SVA/ASP (0.783 hours or 47 minutes) and an SVA/ASP resubmission (0.233 hours or 14 minutes) weighted by the number of respondents that submitted first-time SVAs/ASPs and SVA/ASP resubmissions between CY19 and CY21 which was 0.28 hours[9] [(209 first-time submissions × 0.783 hours) + (2,119 resubmissions × 0.233 hours) ÷ 2,328 total submissions = 0.28 hours].

CISA maintains its assumption, based on previous public comments on this information collection, that for every hour a respondent is logged into the SVA/ASP application, the respondent spends an average of 4 hours in preparation. Therefore, based on the 0.28 hours average log in time for the CSAT SVA/ASP application and the 4 hours of average preparation time, CISA calculates that between CY19 and CY21, the burden per respondent to prepare and submit an SVA/ASP was 1.4136 hours[10] [0.28 hours logged into CSAT + (0.28 hours × 4) for preparation].

Annual Burden Hours: The annual burden hours for an SVA/ASP is 3,291 hours[11] (2,328 respondents × 1 response per respondent × 1.4136 hours per response = 3,291 hours).

Total Annual Burden Cost: CISA assumes that SSOs will be responsible for submitting SVAs/ASPs. For this ICR, CISA maintains this assumption. Therefore, to estimate the total annual burden, CISA multiplied the annual burden of 3,291 hours by the average hourly total compensation rate of SSOs of $90.41 per hour.[12] Therefore, the total annual burden cost for the SVA/ASP is $297,530 (*i.e.,* 3,291 hours multiplied by $90.41 per hour).

Total Burden Cost (Capital/Startup): CISA provides access to CSAT free of charge and CISA assumes that each respondent already has access to the internet for basic business needs. Therefore, CISA estimates that there are no capital/startup costs for this instrument.

Total Recordkeeping Burden: For respondents that are determined by CISA to present a high level of security risk, the SVA/ASP recordkeeping burden is accounted for within the recordkeeping burden estimate for the SSP/ASP discussed below in Subsection 3 of this section. Therefore, CISA estimates that no recordkeeping burden is associated with this instrument.

[7] CISA's adoption of the assumption that for every hour a respondent is logged into the Top-Screen application, SVA/ASP application, and SSP/ASP application, the respondent spends an average of 4 hours in preparation is described in the 30-day notice the Department published for this information collection in March 2013 at 78 FR 16694, which may be viewed at *https://www.federalregister.gov/d/2013-06095.*

[8] Mean hourly wage was obtained from U.S. Department of Labor, BLS; May 2021 Occupational Employment and Wage Statistics, OES Managers, All Other. (Occupational Code 11–9199). Retrieved from *https://www.bls.gov/oes/2021/may/oes_nat.htm.* of $62.36 times the wage rate benefit multiplier of 1.4499 (to account for fringe benefits) equaling $90.4141. The benefits multiplier is estimated by dividing total compensation of $40.35 by salaries and wages of $27.83, based on Employer Cost for Employee Compensation, December 2021, released March 18, 2022 (*https://www.bls.gov/news.release/archives/ecec_03182022.pdf*).

[9] 0.28271 hours.

[10] 1.4136 hours = 0.2827 hours + 1.1308 hours.

[11] 3,290.75 hours.

[12] $90.4142 is the hourly labor costs, including wages and benefits.

3. CISA'S Methodology in Estimating the Burden for the Site Security Plan (SSP) & Alternative Security Program (ASP) Submitted in Lieu of an SSP

Number of Respondents: The current information collection estimated 1,683 SSP/ASP respondents. For this ICR, the Department maintains the assumption that all respondents to the SVA/ASP will be a respondent of the SSP/ASP. Therefore, CISA estimates that the annual number of respondents will be 2,328, which is based on the average number of all respondents to the SVA/ASP. This number breaks down to, on average, 209 initial submissions and 2,119 resubmissions per year.

Estimated Time per Respondent: The current information collection estimated the time per respondent for preparing and submitting an SSP/ASP to be 2.72 hours. For this ICR, CISA estimates the time per respondent for preparing and submitting an SSP/ASP will be 7.845 hours.

CISA intends to make a revision to the SSP/ASP instrument to collect facility internet Protocol (IP) address(es) and Domain Name System (DNS) information. The collection of IP address(es) and DNS information supports the development of a facility's SSP in accordance with 6 U.S.C. 622 (a)(2)(D)(ii) and 6 CFR 27.225(a)(4). In addition, CISA may potentially use this information to integrate with other data within the U.S. Government, conduct related analysis, and provide warnings about cyber threats affecting chemical facilities. CISA expects that answering these questions will not meaningfully increase the estimated SSP/ASP completion time.

Using the data collected between CY 19 and CY 21, CISA obtained the estimate of 7.845 hours by first determining the average amount of time respondent were logged into the SSP/ASP application (1.5689 hours or 94 minutes). CISA calculated the average amount of time respondents were logged into the SSP/ASP application by using the median duration respondents were logged into the SSP/ASP application for an initial SSP/ASP (4.63 hours or 278 minutes) and an SSP/ASP resubmission (1.27 hours or 76 minutes) weighted by the number of respondents that submitted first-time SSPs/ASPs and SSP/ASP resubmissions between CY19 and CY21, which was 1.5689 hours (94 minutes) [(209 first-time submissions × 4.6333 hours) + (2,119 resubmissions × 1.2666 hours) ÷ 2,328 total submissions = 1.5689 hours].

CISA maintains its assumption, based on previous public comments on this information collection, that for every hour a respondent is logged into the SSP/ASP application, the respondent spends an average of 4 hours in preparation. Therefore, based on the 1.57 hours average log in time for the CSAT SSA/ASP application and the 4 hours of average preparation time, CISA calculates that between CY19 and CY21, the burden per respondent to prepare and submit an SSP/ASP was 7.845 hours [1.5689 hours logged into CSAT + (1.5689 hours × 4) for preparation].

Annual Burden Hours: The annual burden hours for SSPs/ASPs is 18,262 hours (2,328 respondents × 1 response per respondent × 7.845 hours per response).

Total Annual Burden Cost: CISA assumes that SSOs will be responsible for submitting SSPs/ASPs. For this ICR, CISA maintains this assumption. Therefore, to estimate the total annual burden, CISA multiplied the annual burden of 18,262 hours by the average hourly total compensation rate of SSOs of $90.41 per hour [13]. Therefore, the total annual burden cost for the SVA/ASP is $ 1,651,158 (*i.e.,* 18,262 hours multiplied by $90.41 per hour).

Total Burden Cost (Capital/Startup): CISA provides access to CSAT free of charge and CISA assumes that each respondent already has access to the internet for basic business needs. Therefore, CISA estimates that there are no capital/startup costs.

Total Recordkeeping Burden: The current information collection estimated a recordkeeping burden of approximately $516,825. For this information collection, CISA estimates a recordkeeping burden of $556,040. CISA maintained the methodology and assumptions described in the current information collection but increased the current estimate to account for updating the hourly compensation rates [14] to $44.18 and inflating the 2017 ICR renewal capital/startup costs by an inflation factor [15] of 1.09.

For this ICR, CISA maintains its approach of accounting for the entire recordkeeping burden imposed on covered chemical facilities under CFATS within the SSP/ASP instrument, because: (1) only covered chemical facilities are required to maintain records; (2) no changes to the recordkeeping requirements have occurred since the approval of the current information collection; and (3) CISA's historical assumption that respondents maintain any other required records in the same manners, formats, and locations as they maintain their SSP/ASP records.

4. CISA'S Methodology in Estimating the Burden for the CFATS Help Desk

Number of Respondents The current information collection estimated that CISA receives 15,000 requests annually for CFATS Help Desk support (*i.e.,* 15,000 respondents via phone calls, emails, and web-based help request forms). CISA is proposing to lower this estimate to 12,000 respondents.

CISA evaluated historical data to determine if the estimated number of CFATS Help Desk requests (*i.e.,* 15,000) was still appropriate. Between CY19 and CY21, the average annual number of CFATS Help Desk requests was 11,819. Therefore, CISA believes that lowering the existing estimate of 15,000 respondents to 12,000 is appropriate.

Estimated Time per Respondent: The current estimated time per respondent for the CFATS Help Desk is 0.17 hours (10 minutes). CISA is proposing to lower this estimate to 0.1167 hours (7 minutes).

CISA evaluated historical data to determine if the estimated time per respondent of 0.17 hours (10 minutes) was still appropriate. Between CY19 and CY21, the average duration for a CFATS Help Desk call was approximately 7 minutes (6 minutes and 46 seconds), which is a slight decrease from the average duration for a CFATS Help Desk call reported by CISA in previous years. CISA does not have any information on the average amount of time it took respondents to type and send emails to the CFATS Help Desk.

Because the average duration for a CFATS Help Desk call remains below the current estimate of 0.17 hours, CISA believes that it is appropriate to lower the estimate for this information collection to 0.1167 hours.

Annual Burden Hours: The average annual burden hours for the CFATS Help Desk will be 1,400 hours [12,000 respondents × 0.1167 hours per respondent = 1,400 hours].

Total Annual Burden Cost: CISA assumes that SSOs will be responsible for contacting the CFATS Help Desk. For this ICR, CISA maintains this

[13] $90.4142 is the hourly labor costs, including wages and benefits.

[14] Mean hourly wage was obtained from U.S. Department of Labor, BLS; May 2021 Occupational Employment and Wage Statistics, OES First-Line Supervisors of Office and Administrative Support Workers, (Occupational Code 43–1011). Retrieved from *https://www.bls.gov/oes/2021/may/oes_nat.htm.* of $30.47 times the wage rate benefit multiplier of 1.4499 (to account for fringe benefits) equaling $44.177. The benefits multiplier is estimated by dividing total compensation of $40.35 by salaries and wages of $27.83, based on Employer Cost for Employee Compensation, December 2021, released March 18, 2022 (*https://www.bls.gov/news.release/archives/ecec_03182022.pdf*).

[15] Federal Reserve Bank of St. Louis, Federal Reserve Economic Data, GDP factor from 2017 to 2021 dollars was 1.0975 = 113.0664÷103.02 *https://fred.stlouisfed.org/series/USAGDPDEFAISMEI.*

assumption. Therefore, to estimate the total annual burden, CISA multiplied the annual burden of 1,400 hours by the average hourly total compensation rate of SSOs of $90.41 per hour.[16] Therefore, the total annual burden cost for the CFATS Help Desk is $126,580 (*i.e.,* 1,400 hours multiplied by $90.41 per hour.

Total Burden Cost (Capital/Startup): Contacting the CFATS Help Desk is free and CISA assumes that each respondent already has a phone or access to the internet for basic business needs. Therefore, CISA estimates that there are no capital/startup costs.

Total Recordkeeping Burden: There is no recordkeeping burden for this instrument.

5. CISA's Methodology in Estimating the Burden for the CSAT User Registration

Number of Respondents: The current information collection estimated 1,000 respondents would complete the user registration process annually. For this ICR, CISA maintains this estimate.

Historically, CISA's estimate in the current information collection was primarily based on the number of individuals expected to register as a CSAT Authorizer, Submitter, and/or Preparer. However, the scope of the CSAT User Registration instrument in the current information collection was intended to allow for the creation of additional CSAT user roles such as the Administrator and Personnel Surety (PS) Submitter user roles. Because the estimate has always been very conservative, for example, between CY19 and CY21 the average annual number of individuals registered was 540. Thus, CISA believes that maintaining the current estimate of 1,000 respondents annually is a reasonable estimate that reflects the user registration activity for all types of CSAT users.

Estimated Time per Respondent: In the current information collection, the estimated time per respondent is 2.5 hours. CISA proposes to maintain the current estimate.

This estimate is based on two factors: (1) the actual time needed to complete the CSAT User Registration process continues to be approximately 0.5 hours (30 minutes); and (2) CISA expects that CSAT Authorizers need additional time to manage the CSAT user accounts for which they are responsible.

The ongoing management of the CSAT user accounts includes activities such as, but not limited to: (1) assigning Submitters and Preparers to facilities; (2) updating the facilities with which a Submitter or Preparer is associated as his or her duties change; (3) creating groups[17] to support the CFATS Personnel Surety (PS) Program; (4) assigning PS Submitters to groups; and (5) updating the PS Submitters' access to groups as their duties change.

CISA intends to revise the user registration instrument to collect facility Employer Identification Numbers (EIN). The collection of EIN information will allow CISA to identify chemical facilities of interest, in accordance with 6 U.S.C. 622(a)(2)(A)(i), within datasets that are in the possession of the Federal Government. CISA expects that answering these questions will not meaningfully increase the estimated time per respondent.

For this ICR, CISA is applying the assumption based on previous public comments on this information collection (*i.e.,* OMB Control No. 1670–0007) that for every hour a respondent is logged into the CSAT application, the respondent spends an average of 4 hours in preparation (*e.g.,* coordinating with CFATS-facility stakeholders, including Human Resources, Procurement, or Contract Administration to explain the PS Program requirements and determine how best to gather the data from different populations). Therefore, CISA's estimated time per respondent is 2.5 hours [0.50 hours logged into CSAT + (0.50 hours × 4) for preparation = 2.5 hours].

Annual Burden Hours: The annual burden estimate for CSAT User Registration is 2,500 hours [1,000 respondents × 1 response per respondent × 2.5 hours per respondent = 2,500 hours].

Total Annual Burden Cost: CISA assumes that SSOs will be responsible for CSAT User Registration. For this ICR, CISA maintains this assumption. Therefore, to estimate the total annual burden, CISA multiplied the annual burden of 2,500 hours by the average hourly total compensation rate of SSOs of $90.41 per hour.[18] Therefore, the total annual burden cost for the CSAT User Registration is $226,035 (*i.e.,* 2,500 hours multiplied by $90.41 per hour).

Total Burden Cost (Capital/Startup): CISA provides access to CSAT free of charge and CISA assumes that each respondent already has access to the internet for basic business needs. Therefore, for this ICR CISA estimates that there are no capital/startup costs for this instrument.

Total Recordkeeping Burden: There is no recordkeeping burden for this instrument.

6. CISA'S Methodology in Estimating the Burden for Identification of Additional Facilities and Assets at Risk

Number of Respondents. The current information collection estimated that each year 3,426 respondents would respond to this instrument. For this ICR, CISA estimates the number of respondents will be 2,252.

This instrument is composed of two sections titled ''Identification of Facilities'' and a second section titled ''Assets at Risk.'' The first section collects information on a voluntary basis when a facility ships and/or receives Chemicals of Interest (COI). The second section collects information on a voluntary basis when the facility identifies a cyber system. The estimate of 2,252 respondents is based upon the sum of 439 respondents for the first section of this instrument and 1,813 respondents for the second section of this instrument.

CISA estimated 439 respondents for the first section of the instrument by using data on the number of compliance inspection conducted between CY 2019 and CY 2021. Between CY19 and CY21, CISA completed an average of 1,021 compliance inspections per year. Of these inspections, approximately 43 percent of the covered chemical facilities inspected ship COI. Therefore, because CISA only requests this information from covered chemical facilities that undergo compliance inspections and ship COI, CISA estimates 439 respondents for the first section of the instrument [1,021 facilities inspected × 43 percent of facilities ship COI = 439].

With respect to the second section of the instrument (''Assets at Risk''), if a covered chemical facility has identified a cyber-related system in their SVA or SSP, CISA may request the information covered under this section of the instrument during interactions that occur during: (1) Compliance Assistance Visits, (2) Authorization Inspections, and (3) Compliance Inspections.[19]

[16] $90.4142 is the hourly labor costs, including wages and benefits.

[17] ''Groups'' is a technical term used by CISA to describe how a covered chemical facility may manage the access to records about affected individuals in the CSAT Personnel Surety application. CISA describes the term ''groups'' and provides additional information about how to create and manage groups in section 9.5 of the CSAT User Manual, which may be viewed at *https://www.dhs.gov/sites/default/files/publications/csat-portal-user-manual-508-2.pdf.*

[18] $90.4142 is the total compensation per hour, including wages and benefits.

[19] This information is not covered under the SSP because the information is not subsequently submitted through the CSAT SSP but rather documented by an inspector or other appropriate employee of CISA.

Between CY 2019 and CY 2021, CISA has performed 5,438 of these interactions at facilities and asked questions about assets at risk. Therefore, CISA estimates 1,813 respondents [20] for the second section of the instrument by annualizing the number of interactions described above (*i.e.,* 1,813 = [5438 respondents divided by a 3-year time-period]).

Estimated Time per Respondent: In the current information collection, the estimated time per respondent is 0.17 hours (10 minutes). In this ICR, CISA maintains this estimate.

Annual Burden Hours: The annual burden estimate is 375 hours [2,252 respondents × 1 response per respondent × 0.17 hours per respondent].

Total Annual Burden Cost: CISA assumes that SSOs will be responsible for providing this information. Therefore, to estimate the total annual burden, CISA multiplied the annual burden of 375 hours by the average hourly total compensation rate of SSOs of $90.41 [21] per hour. Therefore, the total annual burden cost for this instrument is $33,931 (375 hours multiplied by $90.41 per hour).

Total Burden Cost (Capital/Startup): CISA estimates that there are no capital/startup costs for this instrument.

Total Recordkeeping Burden: There is no recordkeeping burden for this instrument.

Public Participation: *OMB is particularly interested in comments that:*

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology (*e.g.,* permitting electronic submissions of responses).

[20] 1,812.67 = (5438 ÷ 3).

[21] $90.4142 is the total compensation per hour, including wages and benefits.

Analysis

Title of Collection: Chemical Security Assessment Tool

OMB Control Number: 1670–0007

Instrument: Top-Screen

Frequency: ''On occasion'' and ''Other''

Affected Public: Business or other for-profit

Number of Respondents: 3,817 respondents (estimate)

Estimated Time per Respondent: 2.04 hours

Total Annual Burden Hours: 7,785 hours

Total Annual Burden Cost: $703,829

Total Annual Burden Cost (capital/startup): $0

Total Recordkeeping Burden: $0

Instrument: Security Vulnerability Assessment and Alternative Security Program submitted in lieu of a Security Vulnerability Assessment

Frequency: ''On occasion'' and ''Other''

Affected Public: Business or other for-profit

Number of Respondents: 2,328 respondents (estimate)

Estimated Time per Respondent: 1.4136 hours

Total Annual Burden Hours: 3,291 hours

Total Annual Burden Cost: $297,530

Total Annual Burden Cost (capital/startup): $0

Total Recordkeeping Burden: $0

Instrument: Site Security Plan and Alternative Security Program submitted in lieu of a Site Security Plan.

Frequency: ''On occasion'' and ''Other''

Affected Public: Business or other for-profit.

Number of Respondents: 2,328 (estimate).

Estimated Time per Respondent: 7.845 hours.

Total Annual Burden Hours: 18,262 hours.

Total Annual Burden Cost: $1,651,158.

Total Annual Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $556,040.

Instrument: CFATS Help Desk

Frequency: ''On occasion'' and ''Other''.

Affected Public: Business or other for-profit.

Number of Respondents: 12,000 respondents (estimate).

Estimated Time per Respondent: 0.1167 hours.

Total Annual Burden Hours: 1,400 hours.

Total Annual Burden Cost: $126,580.

Total Annual Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Instrument: User Registration.

Frequency: ''On occasion'' and ''Other''.

Affected Public: Business or other for-profit.

Number of Respondents: 1,000 respondents (estimate).

Estimated Time per Respondent: 2.5 hours.

Total Annual Burden Hours: 2,500 hours.

Total Annual Burden Cost: $226,035.

Total Annual Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Instrument: Identification of Facilities and Assets at Risk.

Frequency: ''On occasion'' and ''Other''.

Affected Public: Business or other for-profit.

Number of Respondents: 2,252 respondents (estimate).

Estimated Time per Respondent: 0.17 hours.

Total Annual Burden Hours: 375 hours.

Total Annual Burden Cost: $33,931.

Total Annual Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Robert Costello,

Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

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BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2022–0011]

Agency Information Collection Activities: Nationwide Cyber Security Review (NCSR) Assessment

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; Reinstatement Without Change, OMB Control Number: DHS–1670–0040.

SUMMARY: The Joint Cyber Defense Collaborative (JCDC) within Cybersecurity and Infrastructure Security Agency (CISA) will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork

Reduction Act of 1995. CISA previously published this information collection request (ICR) in the **Federal Register** on October 3, 2022 for a 60-day public comment period. Zero comments were received by CISA. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted January 26, 2023. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, Department of Homeland Security and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.* All submissions must include the words ''Department of Homeland Security'' and the OMB Control Number 1670–0040—replace Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: If additional information is required contact: The Department of Homeland Security (DHS), Amy Nicewick at 703–203–0634 or at *CISA.CSD.JCDC_MS-ISAC@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Homeland Security Act of 2002, as amended, established ''a national cybersecurity and communications integration center [''the Center,'' now constituted as CSD] . . . to carry out certain responsibilities of the Under Secretary,'' including the provision of assessments. 6 U.S.C. 659(b). The Act also directs the composition of the Center to include an entity that collaborates with State and local governments on cybersecurity risks and incidents and has entered into a voluntary information sharing relationship with the Center. 6 U.S.C. 659(d)(1)(E). The Multistate Information Sharing and Analysis Center (MS–ISAC) currently fulfills this function. CSD funds the MS–ISAC through a Cooperative Agreement and maintains a close relationship with this entity. As part of the Cooperative Agreement, CISA directs the MS–ISAC to produce the NCSR as contemplated by Congress.

Generally, CSD has authority to perform risk and vulnerability assessments for Federal and non-Federal entities, with consent and upon request. CSD performs these assessments in accordance with its authority to provide voluntary technical assistance to Federal and non-Federal entities. See 6 U.S.C. 659(c)(6). This authority is consistent with the Department's responsibility to ''[c]onduct comprehensive assessments of the vulnerabilities of the Nation's critical infrastructure in coordination with the SSAs [Sector-Specific Agencies] and in collaboration with SLTT [State, Local, Tribal, and Territorial] entities and critical infrastructure owners and operators.'' Presidential Policy Directive (PPD)-21, at 3. A private sector entity or state and local government agency also has discretion to use a self-assessment tool offered by CSD or request CSD to perform an on-site risk and vulnerability assessment. See 6 U.S.C. 659(c)(6). The NCSR is a voluntary annual self-assessment.

In its reports to the Department of Homeland Security Appropriations Act, 2010, Congress requested a Nationwide Cyber Security Review (NCSR) from the National Cyber Security Division (NCSD), the predecessor organization of the Cybersecurity Division (CSD). S. Rep. No. 111–31, at 91 (2009), H.R. Rep. No. 111–298, at 96 (2009). The House Conference Report accompanying the Department of Homeland Security Appropriations Act, 2010 ''note[d] the importance of a comprehensive effort to assess the security level of cyberspace at all levels of government'' and directed DHS to ''develop the necessary tools for all levels of government to complete a cyber network security assessment so that a full measure of gaps and capabilities can be completed in the near future.'' H.R. Rep. No. 111–298, at 96 (2009). Concurrently, in its report accompanying the Department of Homeland Security Appropriations Bill, 2010, the Senate Committee on Appropriations recommended that DHS ''report on the status of cyber security measures in place, and gaps in all 50 States and the largest urban areas.'' S. Rep. No. 111–31, at 91 (2009).

Upon submission of the first NCSR report in March 2012, Congress further clarified its expectation ''that this survey will be updated every other year so that progress may be charted and further areas of concern may be identified.'' S. Rep. No. 112–169, at 100 (2012). In each subsequent year, Congress has referenced this NCSR in its explanatory comments and recommendations accompanying the Department of Homeland Security Appropriations. Consistent with Congressional mandates, CSD developed the NCSR to measure the gaps and capabilities of cybersecurity programs within SLTT governments. Using the anonymous results of the NCSR, CISA delivers a bi-annual summary report to Congress that provides a broad picture of the current cybersecurity gaps & capabilities of SLTT governments across the nation.

The assessment allows SLTT governments to manage cybersecurity related risks through the NIST Cybersecurity Framework (CSF) which consists of best practices, standards, and guidelines. In efforts of continuously providing Congress with an accurate representation of the SLTT gaps and capabilities the NCSR question set may slightly change from year-to-year.

The NCSR is an annual voluntary self-assessment that is hosted on LogicManager, which is a technology platform that provides a foundation for managing policies, controls, risks, assessments, and deficiencies across organizational lines of business. The NCSR self-assessment runs every year from October-February. In efforts to increase participation, the deadline is sometimes extended. The target audience for the NCSR are personnel within the SLTT community who are responsible for the cybersecurity management within their organization.

Through the NCSR, CISA and MS–ISAC will examine relationships, interactions, and processes governing IT management and the ability to effectively manage operational risk. Using the anonymous results of the NCSR, CISA delivers a biannual summary report to Congress that provides a broad picture of the cybersecurity gaps and capabilities of SLTT governments across the nation. The bi-annual summary report is shared with MS–ISAC members, NCSR End Users, and Congress. The report is also available on the MS–ISAC website, *https://www.cisecurity.org/ms-isac/services/ncsr/.*

Upon submission of the NCSR self-assessment, participants will immediately receive access to several reports specific to their organization and their cybersecurity posture. Additionally, after the annual NCSR survey closes, there will be a brief NCSR End User Survey offered to everyone

who completed the NSCR assessment. The survey will provide feedback on participants' experiences, such as how they heard about the NCSR, what they found or did not find useful, how they will utilize the results of their assessment, and other information about their current and future interactions with the NCSR.

The NCSR assessment requires approximately two hours for completion and is located on the LogicManager Platform. During the assessment period, participants can respond at their own pace with the ability to save their progress during each session. If additional support is needed, participants can contact the NCSR helpdesk via phone and email.

The NCSR End User survey will be fully electronic. It contains less than 30 multiple choice and fill-in-the-blank answers and takes approximately 10 minutes to complete. The feedback survey will be administered via Survey Monkey and settings will be updated to opt out of collecting participants' IP addresses. There are no recordkeeping, capital, start-up, or maintenance costs associated with this information collection. There is no submission or filing fee associated with this collection. As all forms are completed via the LogicManager platform and SurveyMonkey, there are no associated collection, printing, or mailing costs. This is a renewal for an existing information collection not a new collection. OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Enhance the quality, utility, and clarity of the information to be collected.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

This is a renewal of an information collection.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title: Nationwide Cyber Security Review Assessment.

OMB Number: CISA–1670–0040.

Frequency: Annually.

Affected Public: State, local, Tribal, and Territorial entities.

Number of Respondents: 3112.

Estimated Time Per Respondent for NCSR Assessment: 2 hours.

Number of Respondents for NCSR End User Survey: 215.

Estimated Time per Respondent for NCSR End User Survey: 0.17 hours (10 minutes).

Total Burden Hours: 6,260.

Total Burden Cost (capital/startup): $389,427 (Capital/Startup).

Total Burden Cost (operating/maintaining): $0 (Operating/Maintaining).

Robert J. Costello,

Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2022–28142 Filed 12–23–22; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–NEW]

Agency Information Collection Activities; New Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until January 26, 2023.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2022–0010. All submissions received must include the OMB Control Number 1615–NEW in the body of the letter, the agency name and Docket ID USCIS–2022–0010.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, Telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Background

On March 15, 2022, President Biden signed the EB–5 Reform and Integrity Act of 2022, Div. BB of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103) into law, which revised INA 203(b)(5). The law immediately repealed the former Regional Center (RC) Program statute at Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act 1993, Public Law 102–395, 106 Stat. 1828, § 610(b).

The law also reauthorized a substantially reformed EB–5 Regional Center (RC) Program which became effective on May 14, 2022. Though USCIS will continue to provide similar services for the newly reformed RC program as it did under the former RC program (such as initial designations, petition adjudications, etc.), the newly

authorized RC program has a different legal framework and requirements from the previously authorized program. Consequently, the current Form I–924 and Form I–924A would not sufficiently collect the necessary information required to adjudicate services under this new program. In an effort to reduce confusion for the services provided in the newly authorized RC program, USCIS discontinued the Form I–924 and Form I–924A collection of information and will be submitting a new information collection under a separate OMB Control Number. Furthermore, the new law included an exemption from the Paperwork Reduction Act for a 1-year period beginning on the date of the enactment of this Act, March 15, 2022. In order to meet the immediate requirements of the Act, the creation of new collections of information to address the newly authorized RC Program were expected to take effect 60 days after the date of the enactment of this Act, May 14, 2022.

Accordingly, USCIS created new forms to address the requirements in the EB–5 Reform and Integrity Act of 2022 and provide services under the newly authorized RC Program. USCIS created five new forms: Form I–956, Application for Regional Center Designation; Form I–956F, Application for Approval of an Investment in a Commercial Enterprise; Form I–956G, Regional Center Annual Statement; Form I–956H, Bona Fides of Persons Involved with Regional Center Program; Form I–956K, Registration for Direct and Third-Party Promoters. USCIS began accepting the new forms upon release after May 14, 2022.

On June 24, 2022, the U.S. District Court for the Northern District of California preliminarily enjoined USCIS from ''treating as deauthorized the previously designated regional centers'' including ''processing new I–526 petitions from immigrants investing through previously authorized regional centers . . . just as the agency would do for a newly approved regional center.'' *Behring* v. *Mayorkas,* Order Granting Plaintiff's Motion for a Preliminary Injunction, Case No. 22-cv-02487–VC (N.D. Cal. Jun 24, 2022). On September 1, 2022, the U.S. District Court in *Behring* approved a settlement between the parties. Under the terms of the settlement, previously designated regional centers did not lose their designation as a result of the EB–5 Reform and Integrity Act of 2022. As USCIS is working to implement the settlement, if it determines changes to the Forms I–956, I–956F, I–956G, I–956H, or I–956K are necessary, it will pursue such changes through either this new form development process or other appropriate mechanism.

Comments

The information collection notice was previously published in the **Federal Register** on September 2, 2022, at 87 FR 54233, allowing for a 60-day public comment period. USCIS received sixteen comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2022–0010 in the search box. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection:

(1) *Type of Information Collection Request:* New Collection.

(2) *Title of the Form/Collection:* Application for Regional Center Designation; Application for Approval of an Investment in a Commercial Enterprise; Regional Center Annual Statement; Bona Fides of Persons Involved with Regional Center Program; Registration for Direct and Third-Party Promoters.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–956; I–956F; I–956G; I–956H; I–956K; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The Form I–956 is used to request U.S. Citizenship and Immigration Services (USCIS) designation as a regional center under Immigration and Nationality Act (INA) section 203(b)(5)(E), or to request an amendment to an approved regional center designated under INA 203(b)(5)(E). The Form I–956F is used by a designated regional center to request approval of each particular investment offering through an associated new commercial enterprise. The Form I–956G is used by regional centers to provide required information, certifications, and evidence to support their continued eligibility for regional center designation. Each approved regional center must file Form I–956G for each Federal fiscal year (October 1 through September 30) on or before December 29 of the calendar year in which the Federal fiscal year ended. The Form I–956H must be completed by each person involved with a regional center, new commercial enterprise, or affiliated job-creating entity and submitted as a supplement to Form I–956, Application for Regional Center Designation, or other forms where persons are required to attest to their eligibility to be involved with the EB–5 entity and compliance with INA section 203(b)(5)(H). The Form I–956K must be completed by each person acting as a direct or third-party promoter (including migration agents) of a regional center, any new commercial enterprise, an affiliated job-creating entity, or an issuer of securities intended to be offered to alien investors in connection with a particular capital investment project.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information

collection I–956 is 400 and the estimated hour burden per response is 23 hours; the estimated total number of respondents for the information collection I–956F is 1,000 and the estimated hour burden per response is 25 hours; the estimated total number of respondents for the information collection I–956G is 643 and the estimated hour burden per response is 16.03 hours; for the audit requirement associated with the I–956G, the estimated total number of respondents for Compliance Review is 40 and the estimated hour burden per response is 24 hours and the estimated total number of respondents for the information collection during the Site Visit is 40 and the estimated hour burden per response is 16 hours; the estimated total number of respondents for the information collection I–956H is 3,643 and the estimated hour burden per response is 1.65 hours; the estimated total number of respondents for the information collection of Biometrics Processing for Form I–956H is 3,643 and the estimated hour burden per response is 1.17 hours; the estimated total number of respondents for the information collection I–956K is 632 and the estimated hour burden per response is 2.04 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 57,657 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $2,907,788.

Dated: December 21, 2022.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–28144 Filed 12–23–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0045]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Petition by Investor To Remove Conditions on Permanent Resident Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until February 27, 2023.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0045 in the body of the letter, the agency name and Docket ID USCIS–2006–0009. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2006–0009.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2006–0009 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* Petition by Investor to Remove Conditions on Permanent Resident Status.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–829; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households; Business or other for-profit. This form is used by a conditional permanent resident who obtained such status through a qualifying investment to apply to remove conditions on their conditional residence.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–829 is 1,010 and the estimated hour burden per response is 3 hours and 48 minutes. The estimated total number of respondents for the information collection of Biometrics is 1,010 and the estimated hour burden per response is 1 hour and 10 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 5,020 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $437,330.

Dated: December 21, 2022.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2022–28152 Filed 12–23–22; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2022–N073; FXES11130300000–223–FF03E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the ESA. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before January 26, 2023.

ADDRESSES:

Document availability and comment submission: Submit requests for copies of the applications and related documents, as well as any comments, by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* ESXXXXXX; see table in **SUPPLEMENTARY INFORMATION**):

- *Email (preferred method): permitsR3ES@fws.gov.* Please refer to the respective application number (*e.g.,* Application No. ESXXXXXX) in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Nathan Rathbun, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Nathan Rathbun, 612–713–5343 (phone); *permitsR3ES@fws.gov* (email). Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite review and comment from the public and local, State, Tribal, and Federal agencies on applications we have received for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17. Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act and the Freedom of Information Act.

Background

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies. Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE 38087B	Jessica Miller, Northfield, OH.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), and gray bat (*Myotis grisescens*).	AL, AR, CT, DC, DE, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, VA, VT, WI, WV, WY.	Conduct presence/absence. surveys, document ..... habitat use, conduct ..... population monitoring, ... and evaluate impacts	Capture with mist-nets, handle, identify, radio-tag,. band, collect nonintrusive. measurements, ... and release	Renew and amend.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE 234121	Western Ecosystem Technology, Inc., Cheyenne, WY.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), gray bat (*Myotis grisescens*), Ozark big-eared bat (*Corynorhinus townsendii ingens*), and Virginia big-eared bat (*Corynorhinus townsendii virginianus*).	AL, AR, CT, DC, DE, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, VA, VT, WI, WV, WY.	Conduct presence/absence. surveys, document ..... habitat use, conduct ..... population monitoring, ... and evaluate impacts	Capture with mist-nets and harp traps,. handle, identify, radio-tag,. band, collect nonintrusive. measurements, ... and release	Renew and amend.
ES26854C	Brenna Hyzy, Minneapolis, MN.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), gray bat (*Myotis grisescens*).	AL, AR, CT, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, MI, ME, MN, MO, MS, NC, ND, NE, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, VT, VA, WI, WV.	Conduct presence/absence. surveys, document ..... habitat use, conduct ..... population monitoring, ... and evaluate impacts	Capture with mist-nets and harp traps,. handle, identify, radio-tag, collect nonintrusive. measurements, ... and release	Renew.
ES30970B	Jefferey Miller, Newnan, GA.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), gray bat (*Myotis grisescens*), Ozark big-eared bat (*Corynorhinus townsendii ingens*), and Virginia big-eared bat (*Corynorhinus townsendii virginianus*).	AR, CT, DE, D.C., IA, IL, IN, KY, MA, MD, MI, ME, MN, MO, ND, NH, NJ, NY, OH, OK, PA, RI, SD, TN, VT, VA, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist-nets and harp traps, handle, identify, radio-tag, band, enter hibernacula, collect nonintrusive measurements, and release.	Renew.
PER0036813	Adam Benshoff, Kent, OH.	Roanoke logperch (*Percina rex*); 32 freshwater mussel species.	AL, AR, CT, DC, GA, IA, KS, KY, IL, IN, LA, MA, MD, MI, MN, MO, MS, NC, NE, NH, NJ, NY, OH, OK, PA, SC, TN, VA, VT, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release, and relocate due to stranding.	New.
TE70488C	Scott Bergeson ..... Fort Wayne, IN	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), and gray bat (*Myotis grisescens*).	AL, AR, CT, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, MI, ME, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, VT, VA, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist-nets and harp traps, handle, identify, radio-tag, band, enter hibernacula, collect nonintrusive measurements, and release.	Renew.
ES64081B	Joseph Hoyt, Blacksburg, VA.	Indiana bat (*Myotis sodalis*) and northern long-eared bat (*Myotis septentrionalis*).	IL, MI, WI	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Enter hibernacula, capture, handle, collect skin swabs.	Renew.
ES40247C	Minnesota Department of Natural Resources, Saint Paul, MN.	Rusty patched bumble bee (*Bombus affinis*).	MN	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release	Renew/ Amend.
ES62286A	Jason Whittle, Richfield, OH.	Indiana bat (*Myotis sodalis*) and northern long-eared bat (*Myotis septentrionalis*).	AL, AR, CN, GA, IL, IN, IA, KY, ME, MD, MA, MI, MS, MO, NH, NJ, NY, NC, OK, OH, PA, SC, TN, VT, VA, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist nets, harp trap, handle, radio-tag, band, collect non-intrusive measurements, collect biological samples and release.	Renew.
ES02651A	Ohio Department of Transportation, Columbus, OH.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), American burying beetle (*Nicrophorus americanus*).	OH	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, radio-tag, release.	Renew.
ES38793A	Kenneth Mierzwa, Eureka, CA.	Hine's emerald dragonfly (*Somatochlora hineana*).	AL, IL, IN, MI, MO, OH, WI.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, release, collect exuviae.	Renew.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
ES151107	Resource Environmental Solutions, Louisville, KY.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), gray bat (*Myotis grisescens*), Ozark big-eared bat (*Corynorhinus townsendii ingens*), and Virginia big-eared bat (*Corynorhinus townsendii virginianus*).	AL, AR, CN, DE, GA, IL, IN, IA, KY, MD, MA, MS, MI, MO, NH, NJ, NY, NC, OK, OH, PA, RI, SC, TN, VT, VA, WV, WI.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist nets, harp trap, handle, radio-tag, band, enter hibernacula, collect non-intrusive measurements, collect biological samples and release.	Renew.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services. USFWS Region 3.

[FR Doc. 2022–28060 Filed 12–23–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX23LR000F60100; OMB Control Number 1028–0059/Renewal]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comprehensive Test Ban Treaty

AGENCY: Geological Survey (USGS), Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the U.S. Geological Survey (USGS) is proposing to renew an Information Collection.

DATES: Interested persons are invited to submit comments on or before January 26, 2023.

ADDRESSES: Send your comments on this Information Collection Request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive, MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–0059 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Elizabeth S. Sangine by email at *escottsangine@usgs.gov,* or by telephone at 703–648–7720. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *https://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA, 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 provides the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on October 18, 2022, 87 FR 63085. We did not receive any public comments in response to that notice.

We are again 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 the USGS minerals information mission; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review,

we cannot guarantee that we will be able to do so.

Abstract: The collection of this information is required by the Comprehensive Test Ban Treaty (CTBT), and will, upon request, provide the CTBT Technical Secretariat with geographic locations of sites where chemical explosions greater than 300 tons TNT-equivalent have occurred.

Title of Collection: Comprehensive Test Ban Treaty.

OMB Control Number: 1028–0059.

Form Number: USGS Form 9–4040–A.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Business or Other-For-Profit Institutions: U.S. nonfuel minerals producers.

Total Estimated Number of Annual Respondents: 2,500.

Total Estimated Number of Annual Responses: 2,500.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 625.

Respondent's Obligation: Voluntary.

Frequency of Collection: Annually.

Total Estimated Annual Nonhour Burden Cost: There are no ''nonhour cost'' burdens associated with this ICR.

An agency may not conduct, sponsor, nor is a person required to respond to a collection of information unless it displays a currently valid OMB control number.

The authorities for this action are the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the National Materials and Minerals Policy, Research and Development Act of 1980 (30 U.S.C. 1601 *et seq.*), the National Mining and Minerals Policy Act of 1970 (30 U.S.C. 21(a)), the CTBT Part III, and the CTBT USGS-Department of Defense Memorandum of Agreement.

Steven Fortier,

Director, National Minerals Information Center, U.S. Geological Survey.

[FR Doc. 2022–28036 Filed 12–23–22; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[223A2100DD/AAKC001030/A0A501010.999900]

Self-Governance PROGRESS Act Negotiated Rulemaking Committee; Notice of Meeting

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Self-Governance PROGRESS Act Negotiated Rulemaking Committee (Committee), will hold the fifth public meeting to negotiate and advise the Secretary of the Interior (Secretary) on a proposed rule to implement the Practical Reforms and Other Goals To Reinforce the Effectiveness of Self-Governance and Self-Determination for Indian Tribes Act of 2019 (PROGRESS Act).

DATES: • *Meeting:* The two-day meeting is open to the public and to be held both in-person and virtually on Wednesday and Thursday, February 1–2, 2023, from 9:00 a.m. to 5:00 p.m. Eastern Standard Time. Please see **SUPPLEMENTARY INFORMATION** below for details on how to participate.

• *Comments:* Interested persons are invited to submit comments on or before March 3, 2023. Please see **ADDRESSES** below for details on how to submit written comments.

ADDRESSES: Send your comments to the Designated Federal Officer, Vickie Hanvey, by any of the following methods:

• *Preferred method:* Email to *comments@bia.gov* with ''PROGRESS Act'' in subject line.

• Mail, hand-carry or use an overnight courier service to the Designated Federal Officer, Ms. Vickie Hanvey, Office of Self-Governance, Office of the Assistant Secretary—Indian Affairs, 1849 C Street NW, Mail Stop 3624, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Vickie Hanvey, Designated Federal Officer, *comments@bia.gov,* (918) 931–0745. Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: This meeting is being held under the authority of the PROGRESS Act (Pub. L. 116–180), the Negotiated Rulemaking Act (5 U.S.C. 561 *et seq.*), and the Federal Advisory Committee Act (5 U.S.C. Appendix 2). The Committee is to negotiate and reach consensus on recommendations for a proposed rule that will replace the existing regulations at 25 CFR part 1000. The Committee will be charged with developing proposed regulations for the Secretary's implementation of the PROGRESS Act's provisions regarding the Department of the Interior's (DOI) Self-Governance Program.

The PROGRESS Act amends subchapter I of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5301 *et seq.,* which addresses Indian Self-Determination, and subchapter IV of the ISDEAA, which addresses DOI's Tribal Self-Governance Program. The PROGRESS Act also authorizes the Secretary to adapt negotiated rulemaking procedures to the unique context of self-governance and the government-to-government relationship between the United States and Indian Tribes. The **Federal Register** (87 FR 30256) notice published on May 18, 2022, discussed the issues to be negotiated and the members of the Committee.

Meeting Agenda

These meetings are open to the public. Detailed information about the Committee, including meeting agendas can be accessed at *https://www.bia.gov/service/progress-act.* Topics for this meeting will include Committee priority setting, possible subcommittees and assignments, negotiated rulemaking process, schedule and agenda setting for future meetings, Committee caucus, and public comment. The Committee meetings will begin at 9:00 a.m. Eastern Standard Time on Wednesday, February 1 and Thursday, February 2, 2023. Members of the public wishing to attend the meeting should visit *https://teams.microsoft.com/l/meetup-join/19%3ameeting_YjAzOGE0NTQtZWViOC00YTM4LWIzOWEtNGY1NzhlMTg2MTky%40thread.v2/0?context=%7b%22Tid%22%3a%220693b5ba-4b18-4d7b-9341-f32f400a5494%22%2c%22Oid%22%3a%2213321130-a12b-4290-8bcf-30387057bd7b%22%2c%22IsBroadcastMeeting%22%3atrue%7d&btype=a&role=a* for virtual access. The public meetings will be held in the 7th floor, South Penthouse Room, located between the 7200 and 7300 corridors, at the Department of the Interior, 1849 C Street NW, Washington, DC 20240.

Meeting Accessibility/Special Accommodations

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to

give DOI sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Comments

Depending on the number of people who want to comment and the time available, the amount of time for individual oral comments may be limited. Requests to address the Committee during the meeting will be accommodated in the order the requests are received. Individuals who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written comments to the Designated Federal Officer up to 30 days following the meeting. Written comments may be sent to Vickie Hanvey listed in the **ADDRESSES** section above.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 5 U.S.C. Appendix 2)

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2022–28092 Filed 12–23–22; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L19900000.PO0000.LLHQ320.22X; OMB Control No. 1004–0073]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Coal Management

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before January 26, 2023.

ADDRESSES: Written comments and recommendations for this information collection request (ICR) should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request additional information about this Information Collection Request (ICR), contact Tom Huebner by email at *thuebner@blm.gov,* or by telephone at (307) 775–6195. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we invite the public and other Federal agencies to comment on new, proposed, revised and continuing collections of information. This helps the BLM assess impacts of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BLM information collection requirements and ensure requested data are provided in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on October 14, 2022, 2022 (87 FR 62440). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies to comment on the proposed ICR described below. The BLM is especially interested in public comment addressing the following:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments submitted in response to this notice are a matter of public record. 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: This collection enables the BLM to learn the extent and qualities of Federal coal resources; evaluate the environmental impacts of coal leasing and development; determine the qualifications of prospective lessees to acquire and hold Federal coal leases; and ensure lessee compliance with applicable statutes, regulations, and lease terms and conditions. This OMB Control Number is currently scheduled to expire on April 30, 2023. The BLM request that OMB renew this OMB Control Number for an additional three years.

Title of Collection: Coal Management (43 CFR parts 3400–3480).

OMB Control Number: 1004–0073.

Form Numbers: 3440–001-Application and License to Mine Coal (Free Use) and Form 3400–012-Coal Lease.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Applicants for, and holders of, coal exploration licenses; applicants/bidders for, and holders of, coal leases; applicants for, and holders of, licenses to mine coal; and surface owners and State and tribal governments whose lands overlie coal deposits.

Total Estimated Number of Annual Respondents: 1,017.

Total Estimated Number of Annual Responses: 1,017.

Estimated Completion Time per Response: Varies from 1 to 800 hours.

Total Estimated Number of Annual Burden Hours: 19,897.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: $943,463.

An agency may not conduct or sponsor and, notwithstanding any other provision of law, 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 PRA of 1995 (44 U.S.C. 3501 *et seq.*).

Darrin King,

Information Collection Clearance Officer.

[FR Doc. 2022–28129 Filed 12–23–22; 8:45 am]

BILLING CODE 4310–84–P

NATIONAL INDIAN GAMING COMMISION

Notice of Approved Class III Tribal Gaming Ordinance

AGENCY: National Indian Gaming Commission.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of the approval of Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation's Class III gaming ordinance by the Chairman of the National Indian Gaming Commission.

DATES: This notice is applicable December 27, 2022.

FOR FURTHER INFORMATION CONTACT: Dena Wynn, Office of General Counsel at the National Indian Gaming Commission, 202–632–7003, or by facsimile at 202–632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) 25 U.S.C. 2701 *et seq.,* established the National Indian Gaming Commission (Commission). Section 2710 of IGRA authorizes the Chairman of the Commission to approve Class II and Class III tribal gaming ordinances. Section 2710(d)(2)(B) of IGRA, as implemented by NIGC regulations, 25 CFR 522.8, requires the Chairman to publish, in the **Federal Register**, approved Class III tribal gaming ordinances and the approvals thereof.

IGRA requires all tribal gaming ordinances to contain the same requirements concerning tribes' sole proprietary interest and responsibility for the gaming activity, use of net revenues, annual audits, health and safety, background investigations and licensing of key employees and primary management officials. The Commission, therefore, believes that publication of each ordinance in the **Federal Register** would be redundant and result in unnecessary cost to the Commission.

Thus, the Commission believes that publishing a notice of approved Class III tribal gaming ordinances in the **Federal Register**, is sufficient to meet the requirements of 25 U.S.C. 2710(d)(2)(B). Every ordinance and approval thereof is posted on the Commission's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances within five (5) business days of approval.

On September 19, 2022, the Chairman of the National Indian Gaming Commission approved Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation's Class III Gaming Ordinance. A copy of the approval letter is posted with this notice and can be found with the approved ordinance on the NIGC's website (*www.nigc.gov*) under General Counsel, Gaming Ordinances. A copy of the approved Class III ordinance will also be made available upon request. Requests can be made in writing to the Office of General Counsel, National Indian Gaming Commission, Attn: Dena Wynn, 1849 C Street NW, MS #1621, Washington, DC 20240 or at *info@nigc.gov.*

National Indian Gaming Commission.

Dated: September 28, 2022.

Michael Hoenig,

General Counsel.

September 19, 2022

Chairman Temet A. Aguilar
Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation
1010 Pauma Reservation Rd,
Pauma Valley, CA 92061
Re: Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation's Amended Gaming Ordinance and Regulations

Dear Chairman Aguilar,

This letter responds to the July 8, 2022 submission on behalf of the Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation (Tribe) informing the National Indian Gaming Commission (NIGC) that the Tribe amended its gaming ordinance and regulations. We understand that these amendments reflect changes in tribal law and ensure consistency with federal and state law as required by its gaming compact with the state of California. Upon review, many of the amendments are technical and non-substantive in nature, with some substantive changes made regarding sovereign immunity, third-party claims, disability and workers' compensation, and structural changes to the Pauma Gaming Commission's composition.

I would like to take this opportunity to remind the Tribe that 25 CFR 522.3 requires that a tribe submit for the Chairman's approval any amendment to an ordinance or resolution within fifteen (15) days after adoption.

Thank you for bringing these amendments to our attention. The amended ordinance and regulations, as noted above, are approved as they are consistent with the requirements of the Indian Gaming Regulatory Act and NIGC's regulations. If you have any questions or require anything further, please contact Logan Cooper at (503) 318–7524 or *Logan.Cooper@nigc.gov.*

Sincerely,

E.Sequoyah: Simermeyer Chairman

[FR Doc. 2022–28049 Filed 12–23–22; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR04093000, XXXR4081G3, RX.05940913.FY19400]

Glen Canyon Dam Adaptive Management Work Group; Notice of Public Meeting

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the Bureau of Reclamation (Reclamation) is publishing this notice to announce that a Federal Advisory Committee meeting of the Glen Canyon Dam Adaptive Management Work Group (AMWG) will take place. The meeting is open to the public.

DATES: The meeting will be held in-person and virtually on Wednesday, February 15, 2023, from 9:30 a.m. to approximately 5:00 p.m. (MST); and Thursday, February 16, 2023, from 9:30 a.m. to approximately 4:00 p.m. (MST).

ADDRESSES: The in-person meeting will be held at the Hilton Garden Inn Phoenix Tempe, University Research Park, 7290 S Price Road, Tempe, AZ 85283.

The virtual meeting held on Wednesday, February 15, 2023, may be accessed at *https://rec.webex.com/rec/j.php?MTID=mf03366db250367070013df04951dab67;* Meeting Number: 2762 685 6744, Password: Feb15.

The virtual meeting held on Thursday, February 16, 2023, may be accessed at *https://rec.webex.com/rec/j.php?MTID=m504b4e2ccb7093a181ea88be7aadef9c;* Meeting Number: 2764 242 1788, Password: Feb16.

FOR FURTHER INFORMATION CONTACT: Ms. Kathleen Callister, Bureau of Reclamation, telephone (801) 524–3781, email at *kcallister@usbr.gov.* Individuals who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: The Glen Canyon Dam Adaptive Management Program (GCDAMP) was implemented as a result of the Record of Decision on the Operation of Glen Canyon Dam Final Environmental Impact Statement to comply with consultation requirements of the Grand Canyon Protection Act (Pub. L. 102–575) of

1992. The AMWG makes recommendations to the Secretary of the Interior concerning Glen Canyon Dam operations and other management actions to protect resources downstream of Glen Canyon Dam, consistent with the Grand Canyon Protection Act. The AMWG meets two to three times a year.

Agenda: The AMWG will meet to receive updates on: (1) current basin hydrology and water year 2023 operations; (2) experiments considered for implementation in 2023; (3) the status of threatened and endangered species; (4) long-term funding considerations; and (5) science results from Grand Canyon Monitoring and Research Center staff. The AMWG will also discuss other administrative and resource issues pertaining to the GCDAMP. To view a copy of the agenda and documents related to the above meeting, please visit Reclamation's website at *https://www.usbr.gov/uc/progact/amp/amwg.html.*

Meeting Accessibility/Special Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: Time will be allowed on both days for any individual or organization wishing to make extemporaneous and/or formal oral comments. To allow for full consideration of information by the AMWG members, written notice should be provided to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice prior to the meeting. Depending on the number of persons wishing to speak, and the time available, the time for individual comments may be limited. Any written comments received will be provided to the AMWG members.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. appendix 2.

William Stewart,

Adaptive Management Group Chief, Upper Colorado Basin—Interior Region 7.

[FR Doc. 2022–28137 Filed 12–23–22; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–562 and 731–TA–1329 (Review)]

Ammonium Sulfate From China; Cancellation of Hearing for Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: Applicable December 1, 2022.

FOR FURTHER INFORMATION CONTACT: Peter Stebbins ((202) 205–2039), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On August 1, 2022, the Commission established a schedule for the conduct of the full five-year reviews (87 FR 47463 August 3, 2022), and on September 19, 2022, gave notice of updated information related to the conduct of the hearing for these reviews (87 FR 58134 September 23, 2022). On November 29, 2022, counsel for the Committee for Fair Trade in Ammonium Sulfate filed a request to appear at the hearing. No other parties submitted a request to appear at the hearing. On December 1, 2022, counsel for the Committee for Fair Trade in Ammonium Sulfate filed a request that the Commission cancel the scheduled hearing for these reviews and withdrew its request to appear at the hearing. Counsel indicated a willingness to submit written responses to any Commission questions. Consequently, the public hearing in connection with these reviews, scheduled to begin at 9:30 a.m. on Tuesday, December 6, 2022, is cancelled. Parties to these reviews should respond to any written questions posed by the Commission in their posthearing briefs, which are due to be filed on December 13, 2022.

For further information concerning these reviews see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: December 2, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–28027 Filed 12–23–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–638 (Fifth Review)]

Stainless Steel Wire Rod From India

Determination

On the basis of the record [1] developed in the subject five-year review, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty order on stainless steel wire rod from India would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted this review on May 2, 2022 (87 FR 25671) and determined on August 5, 2022 that it would conduct an expedited review (87 FR 64246, October 24, 2022).

The Commission made this determination pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determination in this review on December 20, 2022. The views of the Commission are contained in USITC Publication 5396 (December 2022), entitled *Stainless Steel Wire Rod from India: Investigation No. 731–TA–638 (Fifth Review).*

By order of the Commission.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

Issued: December 20, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–28043 Filed 12–23–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1082–1083 (Third Review)]

Chlorinated Isocyanurates From China and Spain

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty orders on chlorinated isocyanurates from China and Spain would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

Background

The Commission instituted these reviews on October 1, 2021 (86 FR 54473) and determined on January 4, 2022 that it would conduct full reviews (87 FR 4290, January 27, 2022). Notice of the scheduling of the Commission's reviews and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 6, 2022 (87 FR 34298). The Commission conducted its hearing on September 29, 2022. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on December 20, 2022. The views of the Commission are contained in USITC Publication 5391 (December 2022), entitled *Chlorinated Isocyanurates from China and Spain: Investigation Nos. 731–TA–1082–1083 (Third Review).*

By order of the Commission.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Chairman David S. Johanson dissenting with respect to the order on chlorinated isocyanurates from Spain. Commissioner Jason E. Kearns not participating.

Issued: December 20, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–28093 Filed 12–23–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2013–0008]

The Benzene Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

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

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Benzene Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by February 27, 2023.

ADDRESSES: *Electronically:* You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov.* Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2013–0008) for the Information Collection Request (ICR). OSHA will place all comments, including any personal information, in the public docket, which may be made available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The following sections describe who uses the information collected under each requirement, as well as how they use it. The purpose of these requirements in the Benzene Standard protects workers from the adverse health effects that may result from occupational exposure to benzene. The major information collection requirements in the Standard include conducting worker exposure monitoring, notifying workers of the benzene exposure, implementing a written compliance program, implementing medical surveillance for workers, providing examining physicians with specific information, ensuring that workers receive a copy of their medical surveillance records, and providing access to these records by OSHA, the National Institute for Occupational Safety and Health, the worker who is the subject of the records,

the worker's representative, and other designated parties.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements contained in the Benzene Standard. The agency is requesting an adjustment decrease of 44,172 burden hours (from 158,770 hours to 114,598 hours). The decrease is due to a reduction in the number of workers exposed above the action level going from 104,093 workers to 69,742 workers. Also, there was an $981,553 decrease in cost under Item 13 from $11,940,431 to $10,958,878. There was a 15 percent increase in medical care services which increased medical exams from $177 to $204 for workers. Also, there was an increase in the number of workers receiving medical examinations.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: Benzene Standard (29 CFR 1910.1028).

OMB Control Number: 1218–0129.

Affected Public: Business or other for-profits.

Number of Respondents: 12,148.

Number of Responses: 223,149.

Frequency of Responses: On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 114,598.

Estimated Cost (Operation and Maintenance): $10,958,878.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); if your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at 202–693–1648. or (3) by hard copy. Please note: While OSHA's Docket Office is continuing to accept and process submissions by regular mail due to the COVID–19 pandemic, the Docket Office is closed to the public and not able to receive submissions to the docket by hand, express mail, messenger, and courier service. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2013–0008). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or a facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so that the agency can attach them to your comments.

Due to security procedures, the use of regular mail may cause a significant delay in the receipt of comments.

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed at Washington, DC.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2022–28052 Filed 12–23–22; 8:45 am]

BILLING CODE 4510–26–P

NUCLEAR REGULATORY COMMISSION

702nd Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232(b)), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on February 1–3, 2023. The Committee will be conducting meetings that will include some Members being physically present at the NRC while other Members participate remotely. Interested members of the public are encouraged to participate remotely in any open sessions via MS Teams or via phone at 301–576–2978, passcode 910547849#. A more detailed agenda including the MS Teams link may be found at the ACRS public website at *https://www.nrc.gov/reading-rm/doc-collections/acrs/agenda/index.html.* If you would like the MS Teams link forwarded to you, please contact the Designated Federal Officer as follows: *Quynh.Nguyen@nrc.gov,* or *Lawrence.Burkhart@nrc.gov.*

Wednesday, February 1, 2023

8:30 a.m.—8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.—10:30 a.m.: Kairos Topical Report on Graphite Materials (Open/Closed)—The Committee will have presentations and discussion with representatives from the NRC staff and Kairos regarding the subject topic.

10:30 a.m.—1:00 p.m.: Committee Deliberation on Kairos Topical Report on Graphite Materials/Lunch (Open/Closed)—The Committee will deliberate regarding the subject topic.

1:00 p.m.—3:00 p.m.: Kairos Topical Report on Metallic Materials (Open/Closed)—The Committee will have presentations and discussion with representatives from the NRC staff and Kairos regarding the subject topic. [**Note:** Pursuant to 5 U.S.C. 552b(c)(4), a

portion of this session may be closed in order to discuss and protect information designated as proprietary.]

3:00 p.m.—6:00 p.m.: Committee Deliberation on Kairos Topical Report on Metallic Materials (Open/Closed)—The Committee will deliberate regarding the subject topic. [**Note:** Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Thursday, February 2, 2023

8:30 a.m.—2:00 p.m.: Oconee Subsequent License Renewal Application Review (Open/Closed) —The Committee will have presentations and discussion with representatives from the NRC staff and licensee regarding the subject topic. [**Note:** Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

2:00 p.m.—6:00 p.m.: Preparation of Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports. [**Note:** Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Friday, February 3, 2023

8:30 a.m.—1:30 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee and Reconciliation of ACRS Comments and Recommendations/Preparation of Reports (Open/Closed)—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings, and/or proceed to preparation of reports as determined by the Chairman. [**Note:** Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]. [**Note:** Pursuant to 5 U.S.C. 552b(c)(2), a portion of this meeting may be closed to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS.]

1:30 p.m.—6:00 p.m.: Preparation of Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on June 13, 2019 (84 FR 27662). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff and the Designated Federal Officer (DFO) (Telephone: 301–415–5844, Email: *Quynh.Nguyen@nrc.gov*), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the cognizant ACRS staff if such rescheduling would result in major inconvenience.

An electronic copy of each presentation should be emailed to the cognizant ACRS staff at least one day before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room (PDR) at *pdr.resource@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System component of NRC's Agencywide Documents Access and Management System, which is accessible from the NRC website at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/#ACRS/.*

Dated: December 20, 2022.

Brooke P. Clark,

Office of the Secretary.

[FR Doc. 2022–28094 Filed 12–23–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of December 26, 2022, January 2, 9, 16, 23, 30, 2023. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Tyesha.Bush@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of December 26, 2022

There are no meetings scheduled for the week of December 26, 2022.

Week of January 2, 2023—Tentative

There are no meetings scheduled for the week of January 2, 2023.

Week of January 9, 2023—Tentative

There are no meetings scheduled for the week of January 9, 2023.

Week of January 16, 2023—Tentative

There are no meetings scheduled for the week of January 16, 2023.

Week of January 23, 2023

Tuesday, January 24, 2023

9:00 a.m. Overview of Accident Tolerant Fuel Activities (Public Meeting) (Contact: Samantha Lav: 301–415–3487)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Thursday, January 26, 2023

9:00 a.m. Strategic Programmatic Overview of the Decommissioning and Low-Level Waste and Nuclear Materials Users Business Lines (Public Meeting) (Contacts: Annie Ramirez: 301–415–6780; Candace Spore: 301–415–8537)

Additional Information: The meeting will be held in the Commissioners'

Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of January 30, 2023—Tentative

There are no meetings scheduled for the week of January 30, 2023.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: December 21, 2022.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2022–28174 Filed 12–22–22; 11:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0221]

Monthly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Monthly notice.

SUMMARY: Pursuant to section 189.a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular monthly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person. This monthly notice includes all amendments issued, or proposed to be issued, from November 4, 2022, to December 8, 2022. The last monthly notice was published on November 29, 2022.

DATES: Comments must be filed by January 26, 2023. A request for a hearing or petitions for leave to intervene must be filed by February 27, 2023.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0221. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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: Kay Goldstein, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1506, email: *Kay.Goldstein@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0221, facility name, unit number(s), docket number(s), application date, and subject 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–2022–0221.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2022–0221, facility name, unit number(s), docket number(s), application date, and subject, in your comment submission.

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 will post all comment submissions at *https://www.regulations.gov* as well as enter 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 submission. 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 into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

For the facility-specific amendment requests shown in this notice, the Commission finds that the licensees' analyses provided, consistent with section 50.91 of title 10 of *the Code of Federal Regulations* (10 CFR) ''Notice for public comment; State consultation,'' are sufficient to support the proposed determinations that these amendment requests involve NSHC. Under the Commission's regulations in 10 CFR 50.92, operation of the facilities in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) involve a significant reduction in a margin of safety.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves NSHC. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final NSHC determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take action on any amendment before 60 days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/cfr.* If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) the name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions that the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one that, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of NSHC, the Commission will make a final determination on the issue of NSHC. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves NSHC, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a petition is submitted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings including documents filed by an interested State,

local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056) and on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9:00 a.m. and 6:00 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The following table provides the plant name, docket number, date of application, ADAMS accession number, and location in the application of the licensees' proposed NSHC determinations. For further details with respect to these license amendment applications, see the applications for amendment, which are available for public inspection in ADAMS. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

LICENSE AMENDMENT REQUEST(S)

Constellation Energy Generation, LLC; Calvert Cliffs Nuclear Power Plant, Units 1 and 2; Calvert County, MD; Constellation Energy Generation, LLC; Peach Bottom Atomic Power Station, Units 2 and 3; York County, PA; Constellation Energy Generation, LLC; R. E. Ginna Nuclear Power Plant; Wayne County, NY

Docket No(s)	50–317, 50–318, 50–277, 50–278, 50–244.
Application date	October 25, 2022.
ADAMS Accession No	ML22298A010.
Location in Application of NSHC	Pages 2–4 of Attachment 1.

LICENSE AMENDMENT REQUEST(S)—Continued

Brief Description of Amendment(s)	The proposed changes incorporate Technical Specification Task Force (TSTF) Improved Standard Technical Specifications Change Traveler TSTF–273–A, ''[Safety Function Determination Program] SFDP Clarifications,'' Revision 2, as amended by [Westinghouse Owners Group-Editorial Change] WOG–ED–23. The proposed changes add explanatory text to the limiting conditions for operation (LCO) 3.0.6 Bases clarifying the ''appropriate LCO for loss of function,'' and that consideration does not have to be made for a loss of power in determining loss of function. Explanatory text is also added to the programmatic description of the SFDP in Technical Specifications (TS) 5.5.15 (Calvert Cliffs Nuclear Power Plant, Units 1 and 2), TS 5.5.11 (Peach Bottom Atomic Power Station, Units 2 and 3), and TS 5.5.14 (R. E. Ginna Nuclear Power Plant) to provide clarification of the same.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jason Zorn, Associate General Counsel, Constellation Energy Generation, 101 Constitution Ave, NW, Washington, DC 20001.
NRC Project Manager, Telephone Number	Scott Wall, 301–415–2855.

Florida Power & Light Company; Turkey Point Nuclear Generating Units 3 and 4; Miami-Dade County, FL

Docket No(s)	50–250, 50–251.
Application date	August 26, 2022.
ADAMS Accession No	ML22243A161 (Package).
Location in Application of NSHC	Pages 12–13 of the Enclosure.
Brief Description of Amendment(s)	The amendments would revise the Turkey Point Nuclear Generating Units 3 and 4, operating license, specifically Paragraph 3.D, Fire Protection, for fire protection program changes that may be made without prior NRC approval. One of the criteria for such a change is that the risk increase resulting from the change is less than 1 × 10–7/year (yr) for Core Damage Frequency and less than 1 × 10–8/yr for Large Early Release Frequency. The change is to support replacement of the currently installed reactor coolant pump (RCP) seals with the Framatome RCP hydrostatic seal package equipped with the Passive Shutdown Seal.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Debbie Hendell, Managing Attorney—Nuclear, Florida Power & Light Company, 700 Universe Blvd., MS LAW/JB, Juno Beach, FL 33408–0420.
NRC Project Manager, Telephone Number	Michael Mahoney, 301–415–3867.

Holtec Decommissioning International, LLC, Holtec Indian Point 2, LLC, and Holtec Indian Point 3, LLC; Indian Point Station Units 1, 2 and 3; Westchester County, NY

Docket No(s)	50–003, 50–247, 50–286.
Application date	May 20, 2022.
ADAMS Accession No	ML22140A126.
Location in Application of NSHC	Pages 7–9 of the enclosure.
Brief Description of Amendment(s)	The proposed amendment would remove the Cyber Security Plan requirements contained in License Condition 3.d of the Indian Point Unit 1 Provisional License, License Condition 2.H of the Indian Point Unit 2 Renewed Facility License, and License Condition 2.G of the Indian Point Unit 3 Renewed Facility License to reflect the guidance on cyber security requirements associated with decommissioning power reactors.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Erin Connolly, Corporate Counsel—Legal, Holtec International, Krishna P. Singh Technology Campus, 1 Holtec Blvd., Camden, NJ 08104.
NRC Project Manager, Telephone Number	Karl Sturzebecher, 301–415–8534.

Holtec Decommissioning International, LLC and Holtec Indian Point 2, LLC; Indian Point Station Unit 2; Westchester County, NY

Docket No(s)	50–247.
Application date	August 2, 2022.
ADAMS Accession No	ML22214A128.
Location in Application of NSHC	Pages 8–18 of enclosure.
Brief Description of Amendment(s)	The proposed amendment would modify the Indian Point Unit 2 (IP2) staffing requirements, prohibit the transfer of Indian Point Unit 3 spent fuel to the IP2 spent fuel pool, and prohibit storing spent fuel in the IP2 spent fuel pool. This change would support transfer of the spent fuel from the IP2 spent fuel pool to dry storage within an independent spent fuel storage installation.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Erin Connolly, Corporate Counsel—Legal, Holtec International, Krishna P. Singh Technology Campus, 1 Holtec Blvd., Camden, NJ 08104.
NRC Project Manager, Telephone Number	Karl Sturzebecher, 301–415–8534.

Virginia Electric and Power Company, Dominion Nuclear Company; North Anna Power Station, Units 1 and 2; Louisa County, VA; Virginia Electric and Power Company; Surry Power Station, Units 1 and 2; Surry County, VA

Docket No(s)	50–280, 50–281, 50–338, 50–339.
Application date	November 7, 2022.
ADAMS Accession No	ML22312A550.
Location in Application of NSHC	Page 32 of 36 of Enclosure 1.
Brief Description of Amendment(s)	The request would modify the Emergency Plan staff augmentation times as described in the amendment request.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	W. S. Blair, Senior Counsel, Dominion Resource Services, Inc., 120 Tredegar St., RS–2, Richmond, VA 23219.
NRC Project Manager, Telephone Number	G. Ed Miller, 301–415–2481.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last monthly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed NSHC determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated in the safety evaluation for each amendment.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to each action, see the amendment and associated documents such as the Commission's letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the following table. The safety evaluation will provide the ADAMS accession numbers for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

LICENSE AMENDMENT ISSUANCE(S)

Constellation Energy Generation, LLC; Clinton Power Station, Unit No. 1; DeWitt County, IL	
Docket No(s)	50–461.
Amendment Date	November 10, 2022.
ADAMS Accession No	ML22292A035.
Amendment No(s)	246.
Brief Description of Amendment(s)	The amendment revised the Clinton Power Station, Unit No. 1, secondary containment design basis to include the Fuel Building Railroad Airlock (FBRA) and FBRA outer door.
Public Comments Received as to Proposed NSHC (Yes/No).	Yes.
Constellation Energy Generation, LLC; Clinton Power Station, Unit No. 1; DeWitt County, IL	
Docket No(s)	50–461.
Amendment Date	November 10, 2022.
ADAMS Accession No	ML22263A473.
Amendment No(s)	247.
Brief Description of Amendment(s)	The amendment modified Technical Specifications (TS) 3.6.2.3, ''Residual Heat Removal (RHR) Suppression Pool Cooling,'' to allow two RHR suppression pool cooling subsystems to be inoperable for 8 hours. The amendment is consistent with NRC-approved Technical Specification Task Force (TSTF) Traveler 230–A, Revision 1, ''Add New Condition B to LCO [Limiting Conditions of Operation] 3.6.2.3, RHR Suppression Pool Cooling.''
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Constellation Energy Generation, LLC; Quad Cities Nuclear Power Station, Units 1 and 2; Rock Island County, IL	
Docket No(s)	50–254, 50–265.
Amendment Date	December 2, 2022.
ADAMS Accession No	ML22308A160.
Amendment No(s)	291 (Unit 1), 287 (Unit 2).
Brief Description of Amendment(s)	The amendments revised the criticality safety analysis (CSA) methodology for performing the criticality safety evaluation for legacy fuel types in addition to the Global Nuclear Fuel Americas, LLC (GNF3) reload fuel in the Quad Cities Nuclear Power Station, Units 1 and 2, spent fuel pool. The amendments also changed the new fuel vault (NFV) CSA for storing GNF3 fuel in the NFV racks.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Constellation Energy Generation, LLC; Quad Cities Nuclear Power Station, Units 1 and 2; Rock Island County, IL	
Docket No(s)	50–254, 50–265.
Amendment Date	December 7, 2022.
ADAMS Accession No	ML22217A044.
Amendment No(s)	292 (Unit 1), 288 (Unit 2).
Brief Description of Amendment(s)	The amendments revised the control rod scram time limits in Quad Cities Nuclear Power Station, Units 1 and 2, technical specification table 3.1.4–1, ''Control Rod Scram Times.''
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Duke Energy Carolinas, LLC; Catawba Nuclear Station, Units 1 and 2; York County, SC; Duke Energy Carolinas, LLC; McGuire Nuclear Station, Units 1 and 2; Mecklenburg County, NC; Duke Energy Carolinas, LLC; Oconee Nuclear Station, Units 1, 2, and 3; Oconee County, SC; Duke Energy Progress, LLC; Brunswick Steam Electric Plant, Units 1 and 2; Brunswick County, NC; Duke Energy Progress, LLC; H. B. Robinson Steam Electric Plant, Unit No. 2; Darlington County, SC; Duke Energy Progress, LLC; Shearon Harris Nuclear Power Plant, Unit 1; Wake and Chatham Counties, NC	
Docket No(s)	50–325, 50–324, 50–413, 50–414, 50–400, 50–369, 50–370, 50–269, 50–270, 50–287, 50–261.
Amendment Date	November 14, 2022.
ADAMS Accession No	ML22256A253.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Amendment No(s)	Brunswick 310 (Unit 1) and 338 (Unit 2); Catawba 315 (Unit 1) and 311 (Unit 2); Shearon Harris 196 (Unit 1); McGuire 325 (Unit 1) and 304 (Unit 2); Oconee 425 (Unit 1), 427 (Unit 2), and 426 (Unit 3); H. B. Robinson 272 (Unit 2).
Brief Description of Amendment(s)	The amendments modified certain technical specification (TS) surveillance requirements (SRs) by adding exceptions to consider the SR met when automatic valves or dampers are locked, sealed, or otherwise secured in the actuated position, in order to consider the SR met based on TS Task Force (TSTF) Traveler TSTF–541, Revision 2, ''Add Exceptions to Surveillance Requirements for Valves and Dampers Locked in the Actuated Position'' (ML19240A315), and the associated NRC safety evaluation for TSTF–541, Revision 2 (ML19323E926).
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Duke Energy Carolinas, LLC; McGuire Nuclear Station, Units 1 and 2; Mecklenburg County, NC

Docket No(s)	50–369, 50–370.
Amendment Date	November 29, 2022.
ADAMS Accession No	ML22290A101.
Amendment No(s)	326 (Unit 1), 305 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Technical Specification 3.4.3, ''RCS [Reactor Coolant System] Pressure and Temperature (P/T) Limits,'' to reflect that the associated figures for Unit 1's effective full power years (EFPY) are applicable up to 54 EFPY, and up to 38.6 EFPY for Unit 2's figures.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Energy Harbor Nuclear Corp. and Energy Harbor Nuclear Generation LLC; Davis-Besse Nuclear Power Station, Unit No. 1; Ottawa County, OH

Docket No(s)	50–346.
Amendment Date	November 15, 2022.
ADAMS Accession No	ML22269A358.
Amendment No(s)	305.
Brief Description of Amendment(s)	The amendment revised the emergency plan for Davis-Besse Nuclear Power Station, Unit No. 1, by changing the emergency response organization staffing requirements.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Energy Northwest; Columbia Generating Station; Benton County, WA

Docket No(s)	50–397.
Amendment Date	November 23, 2022.
ADAMS Accession No	ML22263A445.
Amendment No(s)	268.
Brief Description of Amendment(s)	The amendment revised Columbia Generating Station Technical Specification 3.4.11, ''RCS [Reactor Coolant System] Pressure and Temperature (P/T) Limits,'' to support license renewal.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Entergy Operations, Inc.; Waterford Steam Electric Station, Unit 3; St. Charles Parish, LA

Docket No(s)	50–382.
Amendment Date	November 30, 2022.
ADAMS Accession No	ML22300A208.
Amendment No(s)	269.
Brief Description of Amendment(s)	The amendment modified the licensing basis by adding a license condition to allow for the implementation of the provisions of 10 CFR 50.69 ''Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors.''
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Nebraska Public Power District; Cooper Nuclear Station; Nemaha County, NE

Docket No(s)	50–298.
Amendment Date	November 30, 2022.
ADAMS Accession No	ML22286A207.
Amendment No(s)	272.
Brief Description of Amendment(s)	The amendment revised the Cooper technical specifications (TSs) to adopt Technical Specifications Task Force (TSTF) Traveler TSTF 554, ''Revise Reactor Coolant Leakage Requirements,'' Revision 1. Specifically, the amendment changed the TS definition of ''Leakage,'' clarifying the requirements when pressure boundary leakage is detected, and added a Required Action when pressure boundary leakage is identified.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

NextEra Energy Seabrook, LLC; Seabrook Station, Unit No. 1; Rockingham County, NH

Docket No(s)	50–443.
Amendment Date	December 5, 2022.
ADAMS Accession No	ML22287A157.
Amendment No(s)	171.
Brief Description of Amendment(s)	The amendment revised the ''Steam Generator (SG) Program'' and the ''Steam Generator Tube Inspection Report'' technical specifications for Seabrook Station, Unit No. 1 to adopt the approved Technical Specifications Task Force (TSTF) Traveler TSTF–577, ''Revised Frequencies for Steam Generator Tube Inspections.''

LICENSE AMENDMENT ISSUANCE(S)—Continued

Public Comments Received as to Proposed NSHC (Yes/No).	No.

Pacific Gas and Electric Company; Diablo Canyon Nuclear Power Plant, Units 1 and 2; San Luis Obispo County, CA

Docket No(s)	50–275, 50–323.
Amendment Date	November 16, 2022.
ADAMS Accession No	ML22187A025.
Amendment No(s)	242 (Unit 1), 243 (Unit 2).
Brief Description of Amendment(s)	Upon docketing of the Pacific Gas and Electric Company certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessels, the applicable Diablo Canyon Nuclear Power Plant, Units 1 and 2 (Diablo Canyon) licenses will no longer authorize operation of the reactors or emplacement or retention of fuel into the reactor vessels. The amendments revised the Diablo Canyon Emergency Plan emergency response organization staffing for the post-shutdown and permanently defueled condition. These amendments will not become effective until after docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessels for Diablo Canyon; and the Diablo Canyon Permanently Defueled Technical Specifications are implemented.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Southern Nuclear Operating Company, Inc.; Edwin I. Hatch Nuclear Plant, Units 1 and 2; Appling County, GA

Docket No(s)	50–321, 50–366.
Amendment Date	November 7, 2022.
ADAMS Accession No	ML22293A030.
Amendment No(s)	318 (Unit 1), 263 (Unit 2).
Brief Description of Amendment(s)	The amendments revised technical specifications (TSs) for Hatch, Units 1 and 2, to adopt Technical Specification Task Force (TSTF) Traveler, TSTF–227, involving changes to the End of Cycle Reactor Pump Trip (EOC–RPT) Instrumentation TS, and TSTF–297, involving enhancements to Feedwater and Main Turbine High Water Level Trip, EOC–RPT, and Anticipated Transient Without Scram (ATWS)-RPT TS. Specifically, the amendments add Notes and a new Required Action to allow affected feedwater pump(s) and main turbine valve(s) to be removed from service.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Southern Nuclear Operating Company, Inc.; Joseph M. Farley Nuclear Plant, Units 1 and 2; Columbia, AL

Docket No(s)	50–348, 50–364.
Amendment Date	November 8, 2022.
ADAMS Accession No	ML22308A059.
Amendment No(s)	244 (Unit 1), 241 (Unit 2).
Brief Description of Amendment(s)	The amendments revised the Farley, Units 1 and 2, technical specifications (TS) by relocating some detailed information from TS 5.5.16, ''Main Steamline Inspection Program,'' to the Farley, Units 1 and 2, Updated Final Safety Analysis Report. A program description will remain in TS 5.5.16 for each plant.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 1 and 2; Burke County, GA

Docket No(s)	50–424, 50–425.
Amendment Date	November 8, 2022.
ADAMS Accession No	ML22286A074.
Amendment No(s)	216 (Unit 1), 199 (Unit 2).
Brief Description of Amendment(s)	The amendments revised the Vogtle, Units 1 and 2, technical specifications (TS) by relocating some detailed information from TS 5.5.16, ''MS [Main Steam] and FW [Feedwater] Piping Inspection Program,'' to the Vogtle, Units 1 and 2, Updated Final Safety Analysis Report. A program description will remain in TS 5.5.16 for each plant.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 1 and 2; Burke County, GA

Docket No(s)	50–424, 50–425.
Amendment Date	November 16, 2022.
ADAMS Accession No	ML22286A125.
Amendment No(s)	217 (Unit 1), 200 (Unit 2).
Brief Description of Amendment(s)	The amendments adopted Technical Specification Task Force (TSTF) Traveler 283–A, Revision 3, ''Modify Section 3.8 Mode Restriction Notes'' (ADAMS Accession No. ML003678477) (TSTF–283–A). The amendments modify TS 3.8.1, ''AC Sources—Operating,'' and TS 3.8.4, ''DC Sources—Operating.'' Consistent with TSTF–283–A, Notes were added to allow flexibility in performing Surveillance Requirements in Modes 1 or 2, or in Modes 1, 2, 3, or 4, as applicable.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Susquehanna Nuclear, LLC and Allegheny Electric Cooperative, Inc.; Susquehanna Steam Electric Station, Units 1 and 2; Luzerne County, PA

Docket No(s)	50–387, 50–388.
Amendment Date	November 17, 2022.
ADAMS Accession No	ML22294A150.
Amendment No(s)	284 (Unit 1,) 267 (Unit 2).
Brief Description of Amendment(s)	These amendments revised Technical Specification 5.3.1, ''Unit Staff Qualifications,'' by relocating the specific minimum qualifications for unit staff to the quality assurance program and referring to the quality assurance program for the minimum qualification requirements for comparable positions.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL

Docket No(s)	50–259, 50–260, 50–296.
Amendment Date	November 21, 2022.
ADAMS Accession No	ML22220A260.
Amendment No(s)	322 (Unit 1), 345 (Unit 2), and 305 (Unit 3).
Brief Description of Amendment(s)	The amendments revised some instrument testing and calibration definitions in the Browns Ferry Nuclear Plant, Units 1, 2, and 3, technical specifications (TSs), and incorporated the surveillance frequency control program into a couple of these definitions. The amendments are based on Technical Specification Task Force (TSTF) Traveler TSTF–205–A, Revision 3, ''Revision of Channel Calibration, Channel Functional Test, and Related Definitions,'' and Traveler TSTF–563–A, ''Revise Instrument Testing Definitions to Incorporate the Surveillance Frequency Control Program.'' The amendments also rescinded the consolidation of several surveillance requirements previously approved in Amendment Nos. 315, 338, and 298.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL

Docket No(s)	50–259, 50–260, 50–296.
Amendment Date	November 22, 2022.
ADAMS Accession No	ML22273A103.
Amendment No(s)	323 (Unit 1), 346 (Unit 2), and 306 (Unit 3).
Brief Description of Amendment(s)	The amendments allowed the installation and use of a manually operated chilled water cross-tie line between the Browns Ferry, Unit 3, control bay chilled water system and the Browns Ferry, Units 1 and 2 (1/2), control bay chilled water system to be used when both trains of the Unit 1/2 chilled water system are inoperable. The amendments also revised Browns Ferry, Units 1, 2, and 3, Technical Specification 3.8.7, ''Distribution Systems—Operating,'' to provide a one-time use exception to the Required Actions during the installation and testing of the cross-tie.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Watts Bar Nuclear Plant, Units 1 and 2; Rhea County, TN

Docket No(s)	50–390, 50–391.
Amendment Date	November 4, 2022.
ADAMS Accession No	ML22257A051.
Amendment No(s)	156 (Unit 1), 64 (Unit 2).
Brief Description of Amendment(s)	The amendments revised a few instrument testing and calibration definitions in the Watts Bar Nuclear Plant, Units 1 and 2, technical specifications (TSs), and incorporate the surveillance frequency control program into a few of these definitions. The amendments are based on TS Task Force (TSTF) Traveler TSTF–205–A, Revision 3, ''Revision of Channel Calibration, Channel Functional Test, and Related Definitions,'' and TSTF–563–A, ''Revise Instrument Testing Definitions to Incorporate the Surveillance Frequency Control Program.''
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL; Tennessee Valley Authority; Sequoyah Nuclear Plant, Units 1 and 2; Hamilton County, TN; Tennessee Valley Authority; Watts Bar Nuclear Plant, Units 1 and 2; Rhea County, TN

Docket No(s)	50–259, 50–260, 50–296, 50–327, 50–328, 50–390, 50–391
Amendment Date	December 7, 2022.
ADAMS Accession No	ML22271A914.
Amendment No(s)	Browns Ferry 324 (Unit 1), 347 (Unit 2), 307 (Unit 3); Sequoyah 360 (Unit 1), and 354 (Unit 2); Watts Bar 157 (Unit 1), and 65 (Unit 2)
Brief Description of Amendment(s)	The amendments revised the Tennessee Valley Authority Radiological Emergency Plan emergency action level threshold value for HU2 to provide an additional method to declare the event.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Watts Bar Nuclear Plant, Units 1 and 2; Rhea County, TN

Docket No(s)	50–390, 50–391.
Amendment Date	November 4, 2022.
ADAMS Accession No	ML22257A051.
Amendment No(s)	156 (Unit 1), 64 (Unit 2).
Brief Description of Amendment(s)	The amendments revised a few instrument testing and calibration definitions in the Watts Bar Nuclear Plant, Units 1 and 2, technical specifications (TSs), and incorporate the surveillance frequency control program into a few of these definitions. The amendments are based on TS Task Force (TSTF) Traveler TSTF–205–A, Revision 3, ''Revision of Channel Calibration, Channel Functional Test, and Related Definitions,'' and TSTF–563–A, ''Revise Instrument Testing Definitions to Incorporate the Surveillance Frequency Control Program.''
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Union Electric Company; Callaway Plant, Unit No. 1; Callaway County, MO

Docket No(s)	50–483.
Amendment Date	December 2, 2022.
ADAMS Accession No	ML22301A007.
Amendment No(s)	229.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Brief Description of Amendment(s)	The amendment revised the technical specification requirements to permit the use of risk informed completion times for actions to be taken when limiting conditions for operation are not met and eliminated second completion times.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Wolf Creek Nuclear Operating Corporation; Wolf Creek Generating Station, Unit 1; Coffey County, KS

Docket No(s)	50–482.
Amendment Date	November 4, 2022.
ADAMS Accession No	ML22252A151.
Amendment No(s)	234.
Brief Description of Amendment(s)	The amendment revised Technical Specification 3.8.1, ''AC [alternating current] Sources—Operating,'' by removing the requirements associated with the Sharpe Station gensets and extending the completion time for one inoperable diesel generator from 72 hours to 14 days based upon the availability of a supplemental AC power source (*i.e.*, station blackout diesel generator system). The amendment also deleted the license conditions associated with Amendment No. 163, which added requirements for the Sharpe Station.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Dated: December 21, 2022.

For the Nuclear Regulatory Commission.

Bo M. Pham,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2022–28141 Filed 12–23–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[EA–22–003; NRC–2022–0196]

In the Matter of Cabell Huntington Hospital

AGENCY: Nuclear Regulatory Commission.

ACTION: Confirmatory order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a Confirmatory Order to Cabell Huntington Hospital (CHH) to memorialize the agreement reached during an alternative dispute resolution mediation session held on August 24, 2022. The Confirmatory Order contains commitments made to resolve 14 apparent violations of NRC requirements related to the development and implementation of CHH's radiation protection program, CHH's compliance with occupational dose limits, and CHH's possession of licensed material at an unauthorized location. These violations were identified during NRC inspections and an investigation conducted by the NRC Office of Investigations. The Confirmatory Order is effective upon issuance.

DATES: The Confirmatory Order was issued on November 10, 2022.

ADDRESSES: Please refer to Docket ID NRC–2022–0196 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0196. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the ''For Further Information Contact'' section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Document collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays

FOR FURTHER INFORMATION CONTACT: Cherie Crisden, Region I, U.S. Nuclear Regulatory Commission, 475 Allendale Road, Suite 102, King of Prussia, PA 19406; telephone: 610–337–5061, email: *Cherie.Crisden@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated: December 21, 2022.

For the Nuclear Regulatory Commission.

Raymond K. Lorson,

Regional Administrator, NRC Region I.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE RD, STE 102
KING OF PRUSSIA, PA 19406-1415

November 10, 2022

EA-22-003
NMED NO. 210483 (closed)

Tim Martin, Chief Operating Officer
Cabell Huntington Hospital
1340 Hal Greer Boulevard
Huntington, West Virginia 25701

SUBJECT: CONFIRMATORY ORDER RELATED TO NRC INSPECTION REPORT NO. 03003370/2021001 AND NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2021-015

Dear Tim Martin:

The enclosed Confirmatory Order is being issued to Cabell Huntington Hospital (CHH) as a result of a successful Alternative Dispute Resolution (ADR) mediation session. The commitments in the Confirmatory Order were made by you as part of a settlement agreement with the U.S. Nuclear Regulatory Commission (NRC). The mediation was related to apparent violations of NRC requirements identified in Inspection Report No. 03003370/2021001 and NRC Office of Investigations (OI) Report No. 1-2021-015 and described in an NRC letter dated June 22, 2022 (ML22173A063).[1] The inspection report and a factual summary of the OI investigation were provided as enclosures to the June 22nd letter.

The inspection report documented the results of a routine radiation safety inspection conducted in May 2021, to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements and with the conditions of your license. The inspection consisted of selected examinations of procedures and representative records, observations of activities, independent radiation measurements, and interviews with personnel. Additionally, the report documented the results of further NRC inspection activities associated with one reportable event (a CHH report to the NRC on October 23, 2021, of an overexposure to an authorized user of Yttrium-90) and one incident (receipt of licensed material at an unauthorized location on November 8, 2021) that occurred after the routine inspection. The purpose of the OI investigation was to determine whether willfulness was associated with apparent failures of authorized users to wear dosimetry during Y-90 administrations at CHH facilities. The investigation concluded that for periods of time between May 2018, to May 2021, an authorized user deliberately failed to wear dosimetry during Y-90 procedures. A final enforcement action to the individual will be handled separately.

[1] Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS.

In the June 22, 2022, letter, the NRC informed CHH that 14 apparent violations were identified, of which 11 were being considered for escalated enforcement action, including a civil penalty, in accordance with the NRC Enforcement Policy. The letter also stated that one of the apparent violations being considered for escalated enforcement was determined to be willful. In the letter, the NRC provided CHH the option of participating in a pre-decisional enforcement conference or requesting ADR mediation with the NRC in an attempt to resolve the issues. In response to the NRC's letter, CHH requested ADR. An ADR mediation session was consequently held on August 24, 2022, and a preliminary settlement agreement was reached. As evidenced by the signed "Consent and Hearing Waiver Form" (Enclosure 2), dated November 7, 2022, you have agreed to issuance of the Confirmatory Order (Enclosure 1). The Confirmatory Order confirms the commitments made as part of the preliminary settlement agreement with the agreed-upon modifications.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Confirmatory Order shall be subject to criminal prosecution, as set forth in that section. Violation of this Confirmatory Order may also subject the person to civil monetary penalties.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice", a copy of this letter, along with its enclosures, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, if you choose to respond to this letter, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/.

Sincerely,

/RA/ Original Signed by

Raymond K. Lorson
Deputy Regional Administrator

Enclosures:
1. Confirmatory Order
2. Consent and Hearing Waiver Form

Docket No. 030-03370
License No. 47-00404-02

cc w/encl: James Norweck, M.S., DABR, Radiation Safety Officer
Tera Patton, State of West Virginia

United States of America

Nuclear Regulatory Commission

In the Matter of: CABELL HUNTINGTON HOSPITAL

Docket No. 03003370
License No. 47–00404–02
EA–22–003

Confirmatory Order Modifying License (Effective Upon Issuance)

I

Cabell Huntington Hospital (CHH) is the holder of byproduct materials License No. 47–00404–02 issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to Part 35 of *Title 10 of the Code of Federal Regulations* (10 CFR), ''Medical Use of Byproduct Material.'' The license authorizes the use of byproduct materials by CHH, in accordance with conditions specified therein. CHH has multiple medical facilities in West

Virginia and is authorized to possess and use byproduct material for diagnostic and therapeutic medical uses.

This Confirmatory Order is the result of an agreement reached during an Alternative Dispute Resolution (ADR) mediation session conducted on August 24, 2022.

II

On June 22, 2022, the NRC issued Inspection Report No. 03003370/2021001 to CHH. The report documented the results of a routine inspection in May 2021, that reviewed the activities performed under the NRC license held by CHH to ensure that activities were performed in accordance with NRC requirements and with the conditions of the license. The inspection report also documented the results of additional NRC inspection activities associated with a CHH report to the NRC on October 23, 2021, concerning an overexposure to an authorized user (AU) of Yttrium-90 (Y–90), and an incident on November 8, 2021, involving the receipt of licensed material at an unauthorized location.

In addition to the inspection, on June 21, 2021, the NRC's Office of Investigations (OI) opened an investigation (OI Case No. 1–2021–015) to determine whether interventional radiologists (IRs) who were authorized users of Y–90 at CHH deliberately failed to wear their supplied dosimetry when administering Y–90 and whether the Radiation Safety Officer (RSO) deliberately failed to require interventional radiologists to wear their dosimetry during Y–90 procedures.

Based on the results of the inspection and investigation, the NRC identified 14 apparent violations, of which 11 were considered for escalated enforcement action. One of the apparent violations being considered for escalated enforcement was determined to be willful. This violation involved CHH's failure to monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee, as required by 10 CFR 20.1502(a)(1), and the apparent willful failure to wear dosimetry by an authorized user of Y–90. Although the violation was determined to be willful, it did not adversely impact patient safety. The other 10 violations considered for escalated enforcement involved CHH's failure to: (1) Develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR part 20; (2) provide the RSO with sufficient management prerogative to identify radiation safety problems and stop unsafe operations; (3) instruct individuals who are likely to receive in a year an occupational dose in excess of 100 mrem in the applicable provisions of NRC regulations and requirements in its license for the protection of personnel from exposure to radiation and/or radioactive material; (4) reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person; (5) control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rem shallow-dose equivalent; (6) control the occupational dose to individual adults to an annual dose limit of 5 rem total effective dose equivalent; (7) control the occupational dose to the lens of the eye of individual adults to an annual dose limit of 15 rem dose equivalent; (8) confine possession and use of byproduct materials to the locations and purposes authorized by its license; (9) control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage; and (10) comply with the applicable requirements of the Department of Transportation regulations appropriate to the mode of transport. By letter dated June 22, 2022, the NRC notified CHH of the results of the inspection and OI investigation and offered CHH the opportunity to (1) attend a predecisional enforcement conference or (2) participate in an ADR mediation session, in an effort to resolve these concerns.

In response to the NRC's letter, CHH requested the use of the NRC's ADR process. On August 24, 2022, the NRC and CHH met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. The ADR process is one in which a neutral mediator, with no decision-making authority, assists the parties in reaching an agreement on resolving any differences regarding the dispute. This confirmatory order is issued pursuant to the agreement reached during the ADR process.

III

During the ADR mediation session, CHH and the NRC reached a preliminary settlement agreement. The elements of that agreement are set forth below:

Whereas the NRC acknowledges that CHH has taken several corrective actions in response to the violations so as to preclude the occurrence of similar violations in the future. These corrective actions were documented in Inspection Report 03003370/2021001 dated June 22, 2022. In addition to actions described in the report, CHH created and filled a full-time Assistant Radiation Safety Officer position to assist in the implementation of its Radiation Protection Program, in addition to other actions that were described at the ADR session conducted on August 24, 2022.

Select corrective actions [already completed and described during the ADR session] are described below:

1. CHH developed a centralized radiation safety policy titled ''Mountain Health Network Comprehensive Radiation Safety Policy'' that applies to all CHH facilities. The policy includes instructions on the use of dosimetry, compliance requirements with the licensee's occupational monitoring program, and additional detail on indicators of improper dosimeter use. CHH has also instituted an ALARA [as low as reasonably achievable] review process for unused or unusually low dosimetry results.

2. CHH developed and assigned an electronic training module to the [lR AUs] that provides instruction on the proper use of dosimetry.

3. One [AU] that had exceeded occupational dose limits in calendar year (CY) 2021 was not permitted to work with licensed material for the remainder of CY 2021.

4. CHH provided in-person instruction to supply chain and security staff instructing them to not transport radioactive material to or from CHH facilities.

5. CHH has created an electronic learning module that will be assigned to all staff and will communicate that radioactive material is not to be transported to or from CHH facilities by staff.

6. CHH revised its policy titled ''Ordering and Receiving Radioactive Material'' to include additional communication information and cautions. Additionally, the policy has been revised to include a system for ordering lr-192 sources.

7. CHH revised its policy titled ''Safely Opening Radioactive Material Packages'' to include [receipt of] lr-192 sources.

8. CHH created a policy regarding the shipping and receiving of lr-192 sources.

9. CHH restructured its Radiation Safety Committee such that it is now a single committee with oversight of all authorized locations of use.

Therefore, the parties agree to the following terms and conditions:

I. Terms and Conditions to be taken by CHH

A. Development of a Resource Plan

1. CHH shall review the Radiation Protection Program oversight functions of the RSO and develop a resource plan to ensure compliance with NRC requirements. CHH shall review the appliable guidance in NUREG–1556, ''Consolidated Guidance About Materials Licenses,'' to determine the activities required to be performed by the RSO and to evaluate the resources needed to ensure those activities are adequately completed.

Within 30 days of the effective date of the confirmatory order, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator, along with a copy of the resource plan. The resource plan shall include the individuals' names, qualifications, and time commitment. The reporting structure of the qualified individuals must be documented in the resource plan. The resource plan shall be maintained and made available for NRC inspection for a period of three years after the date of submission of the resource plan to the NRC.

Beginning one year after the date of submission of the resource plan to the NRC, CHH shall review annually and document planned versus actual resources expended by December 31, 2023, and December 31, 2024. The results of these reviews shall be made available for NRC inspection for a period of three years after the date of submission of the resource plan to the NRC.

B. Radiation Safety Committee Charter Development and Implementation

1. CHH shall develop and, after receipt of NRC approval, implement a Radiation Safety Committee (RSC) charter. The charter shall include clearly defined RSC's membership with documented roles and responsibilities for each member, including deliverables and accountability expectations. The charter shall also identify a CHH senior manager to serve as the chairman of the RSC, a reporting structure of the RSC, and applicable training requirements for all RSC members on the roles and responsibilities of their positions within the RSC.

Within 180 days of the effective date of the confirmatory order, CHH shall inform the NRC that CHH has developed an RSC charter by sending a letter to the Region I Administrator and submitting the RSC charter and associated member training materials for NRC review and approval (prior to initial implementation). CHH will notify the NRC in writing of any changes to the RSC charter for a period of up to three years from the date of the receipt of NRC approval of the RSC charter.

2. CHH shall maintain copies of RSC member training materials for a period of 3 years after a training has been conducted for review during NRC inspection. Records of training participation shall include the individual's name, title, and date of training; these records shall also be maintained by CHH and made available during NRC inspection for 3 years after the associated training has been conducted.

C. Third Party Audit

1. Within 360 days of the effective date of the confirmatory order, CHH shall have one or more independent third-party national consulting firms complete [an audit] of CHH's radiation protection program. The audit shall focus on identifying issues and providing recommendations to the licensee. The audit shall include, at a minimum, the following elements:

a. The authority and oversight of the consultant RSO and the adequacy of the RSO contract.

b. The process and procedures for ordering and receiving various types of radioactive material, including the different methods for purchasing and receiving radioactive material, and how communication impacts this process.

c. The occupational monitoring program, to include an assessment of the adequacy of procedures, dosimetry selection, and program implementation.

d. CHH's nuclear safety culture relative to the NRC's safety culture policy statement (*https://www.nrc.gov/about-nrc/safety-culture/sc-policy-statement.html*) or equivalent. Specifically, the audit shall identify organizational opportunities to improve nuclear safety culture. This would include training for applicable radiation safety staff and the need for workshops for CHH leadership, as appropriate.

2. CHH shall submit the name and qualifications of the third-party consultant(s) for NRC approval within 90 days of the effective date of the confirmatory order.

3. Within 45 days of completing the third-party audit pursuant to Section I.C.1, CHH shall inform the NRC that the third-party audit is complete by sending a letter to the Region I Administrator. CHH shall maintain and make the results of the audit, including any non-compliances identified, recommendations, and any corrective actions taken or not taken (and why such action was not taken) as a result of the audit, and a copy of the planned actions available for review during NRC inspection for a period of 3 years from the date of NRC notification pursuant to Section I.C.3.

D. Program Assessment

1. Within 180 days of the effective date of the confirmatory order, CHH shall complete a review of the radiation protection program. Specifically, CHH shall analyze, as part of this review, what actions would be needed for it to shift to performance-based oversight of radiation protection, with clear expectations for continuous improvement. The review shall address, at a minimum, whether the following actions would be warranted to implement a performance-based approach: unannounced area audits, process audits, walk downs by management, 1:1 meetings when new managers become responsible for elements of the radiation protection program, processes for determining how to handle areas of non-compliance, and ALARA investigations of abnormal dosimetry results. At a minimum, the radiation protection program shall include documentation of the responsible individual(s), assessment objectives, minimum criteria to consider an assessment complete, frequency of each assessment, action to be taken when findings occur, management and RSC notification of assessment findings.

2. Within 90 days of completing the review pursuant to Section I.D.1, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator, with a written copy of CHH's radiation protection policies and procedures, specifying any revisions made in response to the review conducted pursuant to Section I.D.1. Any policies, findings, and related documentation shall be maintained and made available for NRC inspection for a period 3 years following completion of this action.

E. Training Program

Within 270 days of the effective date of the confirmatory order, CHH shall complete a review of its current radiation protection training program and revise it consistent with the guidance provided in NUREG–1556. Specifically, the review shall assess the sufficiency of training, shall be informed by the results of any periodic assessments of the radiation protection program, and shall establish record-keeping requirements.

1. Within 30 days of completing the review, CHH shall inform the NRC of the completion of the review by sending a letter to the Region I Administrator

documenting any planned changes to its training program. The letter shall include a description of the standards used to inform the scope and conduct of the review. CHH shall maintain and make its radiation protection training program, along with associated radiation protection training materials, available to the NRC for inspection for a period of three years after notification to the NRC of the completion of the review.

F. External Communication

1. Within 720 days of the effective date of the confirmatory order, CHH shall have conducted the following communications of the importance of ALARA practices with applicable industry clinicians/physician related organizations. Specifically:

a. CHH shall have attempted at least three times to provide a presentation to a national organization that has a membership comprised of physician authorized users of byproduct material. The presentation shall include a description of the reported exposure received by an AU at CHH including the practice used (*i.e.,* hand in the beam), magnitude of exposure, lessons learned, the importance of adherence to NRC requirements for occupational monitoring, and related corrective actions undertaken by CHH. Within 30 days of completing the presentation, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the presentation materials available to the NRC for three years after the presentation for review during NRC inspection. Presentation materials shall consist of a slide show, at a minimum. If the presentation has not been accepted after three submission attempts by CHH to different national organizations, then CHH shall notify the NRC by sending a letter to the Region I Administrator, including with the letter the rejected presentation proposals, as well as intended presentation materials.

b. CHH shall have attempted at least three times to publish a paper in a journal that has a readership comprised of physician authorized users of byproduct material. The paper shall include a description of the reported exposure received by an AU at CHH including the practice used (*i.e.,* hand in the beam), magnitude of exposure, lessons learned, the importance of adherence to NRC requirements for occupational monitoring, and related corrective actions undertaken by CHH. Within 30 days of submitting the paper, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the paper available to the NRC for three years after the paper is submitted for review during NRC inspection. If the paper has not been accepted for publication after three submission attempts have been made by CHH to different journals, then CHH shall notify the NRC by sending a letter to the Region I Administrator, all with copies of all versions of the paper tendered for publication.

2. As specified below, CHH shall discuss the issues it encountered related to the maintenance of its radiation protection program:

a. Within 720 days of the effective date of the confirmatory order, CHH shall have attempted at least three times to provide a presentation describing the issues related to the maintenance of its radiation protection program, resolution of the issues, and the path to compliance to a national organization that has a membership comprised of health physics and radiation professionals. Within 30 days of completing this presentation, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the presentation materials available to the NRC for three years after the presentation for review during NRC inspection. Presentation materials shall consist of a slide show, at a minimum. If the presentation has not been accepted after three submission attempts by CHH to different national organizations, then CHH shall notify the NRC by sending a letter to the Region I Administrator, including with the letter the rejected presentation proposals, as well as intended presentation materials.

b. Within 720 days of the effective date of the confirmatory order, CHH shall have attempted at least three times to have a paper published by a national journal that has a readership comprised of health physics and radiation professionals related to the issues related to the maintenance of its radiation protection program, resolution of the issues, and the path to compliance. Within 30 days of a paper submission attempt, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the paper available to the NRC for three years after the paper is submitted for review during NRC inspection. If the paper has not been accepted for publication after three submission attempts have been made by CHH to different journals, then CHH shall notify the NRC by sending a letter to the Region I Administrator, along with copies of all versions of the paper tendered for publication.

II. Terms and Conditions To Be Taken by NRC

1. The NRC agrees not to issue a civil penalty and does not intend to take further action for the violations described in inspection report 03003370/2021001.

2. The NRC agrees to not issue a separate Notice of Violation in addition to the confirmatory order but, rather, to describe the violations in the body of the confirmatory order instead. The description will include that one of the violations involved the deliberate actions of a non-employee authorized user for failure to wear required occupational dose monitoring devices and that this violation did not impact patient care.

3. For the NRC's future civil penalty assessment purposes as discussed in the NRC Enforcement Policy, the NRC agrees that the issuance of this Confirmatory Order will be considered as escalated enforcement.

4. The NRC will issue a press release to coincide with the issuance of the confirmatory order.

5. In the event of the transfer of the license of Cabell Huntington Hospital to another entity, the terms and conditions set forth hereunder shall continue to apply to the Cabell Huntington Hospital and accordingly survive any transfer of ownership or license.

On November 7, 2022, CHH consented to issuing this Confirmatory Order with the commitments, as described in Section V below. CHH further agrees that this Confirmatory Order is to be effective upon issuance, the agreement memorialized in this Confirmatory Order settles the matter between the parties, and that CHH has waived its right to a hearing.

IV

Because CHH has agreed to take additional actions to address NRC concerns, as set forth in Section III above, the NRC has concluded that its concerns can be resolved through issuance of this Confirmatory Order.

The NRC finds that CHH's actions completed, as described in Section III above, combined with the commitments as set forth in Section V, are acceptable and necessary; the NRC concludes that with these commitments in place the public health and safety will be reasonably assured. In view of the foregoing, the NRC has determined that public health and safety require that CHH's commitments be confirmed by this Confirmatory Order. Based on the above and CHH's consent, this

Confirmatory Order is effective upon issuance.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 30, *It Is Hereby Ordered*, Effective Upon Issuance, That License No. 47–00404–02 Is Modified as Follows:

A. Development of a Resource Plan

1. CHH shall review the Radiation Protection Program oversight functions of the RSO and develop a resource plan to ensure compliance with NRC requirements. CHH shall review the appliable guidance in NUREG–1556 to determine the activities required to be performed by the RSO and to evaluate the resources needed to ensure those activities are adequately completed.

Within 30 days of the effective date of the Confirmatory Order, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator, along with a copy of the resource plan. The resource plan shall include the individuals' names, qualifications, and time commitment. The reporting structure of the qualified individuals must be documented in the resource plan. The resource plan shall be maintained and made available for NRC inspection for a period of three years after the date of submission of the resource plan to the NRC.

Beginning one year after the date of submission of the resource plan to the NRC, CHH shall review planned versus actual resources expended during calendar year 2023 and document the findings of the review by December 31, 2023. CHH shall perform a similar review for calendar year 2024 and document the findings by December 31, 2024. The results of these reviews shall be made available for NRC inspection for a period of three years after the date of submission of the resource plan to the NRC.

B. Radiation Safety Committee (RSC) Charter Development and Implementation

1. CHH shall develop and, after receipt of NRC approval (as described below), implement an RSC charter. The charter shall include clearly defined RSC's membership with documented roles and responsibilities for each member, including deliverables and accountability expectations. The charter shall also identify a CHH senior manager to serve as the chairman of the RSC, a reporting structure of the RSC, and applicable training requirements for all RSC members on the roles and responsibilities of their positions within the RSC.

Within 180 days of the effective date of the Confirmatory Order, CHH shall inform the NRC that CHH has developed an RSC charter by sending a letter to the Region I Administrator and submitting the RSC charter and associated member training materials for NRC review and approval (prior to initial implementation). CHH will notify the NRC in writing of any changes to the RSC charter for a period of up to three years from the date of the receipt of NRC approval of the RSC charter.

2. CHH shall maintain copies of RSC member training materials for a period of 3 years after a training has been conducted for review during NRC inspection. Records of training participation shall include the individual's name, title, and date of training; these records shall also be maintained by CHH and made available during NRC inspection for 3 years after the associated training has been conducted.

C. Third Party Audit

1. Within 360 days of the effective date of the Confirmatory Order, CHH shall engage at least one independent third-party national consulting firm to complete an audit of CHH's radiation protection program. The audit shall focus on identifying issues and providing recommendations to the licensee. The audit shall include, at a minimum, the following elements:

a. The authority and oversight of the consultant RSO and the adequacy of the RSO contract.

b. The process and procedures for ordering and receiving various types of radioactive material, including the different methods for purchasing and receiving radioactive material, and how communication impacts this process.

c. The occupational monitoring program, to include an assessment of the adequacy of procedures, dosimetry selection, and program implementation.

d. CHH's nuclear safety culture relative to the NRC's safety culture policy statements *https://www.nrc.gov/about-nrc/safety-culture/sc-policy-statement.html* or equivalent. Specifically, the audit shall identify organizational opportunities to improve nuclear safety culture. This would include training for applicable radiation safety staff and the need for workshops for CHH leadership, as appropriate.

2. CHH shall submit the name and qualifications of the third-party consultant(s) for NRC approval within 90 days of the effective date of the Confirmatory Order.

3. Within 45 days of completing the third-party audit pursuant to Section V.C.1, CHH shall inform the NRC that the third-party audit is complete by sending a letter to the Region I Administrator. CHH shall maintain and make the results of the audit, including any findings identified, recommendations, and any corrective actions taken or not taken (and why such action was not taken) as a result of the audit, and a copy of the planned actions, available for review during NRC inspection for a period of 3 years from the date of NRC notification pursuant to Section V.C.3.

D. Program Assessment

1. Within 180 days of the effective date of the Confirmatory Order, CHH shall complete an assessment of its radiation protection program. Specifically, CHH shall analyze, as part of this assessment, what actions would be needed for it to shift to performance-based oversight of radiation protection, with clear expectations for continuous improvement. The assessment shall address, at a minimum, whether the following actions would be warranted to implement a performance-based approach: unannounced area audits, process audits, walk downs by management, one-on-one meetings when new managers become responsible for elements of the radiation protection program, processes for determining how to handle areas of non-compliance, and ALARA investigations of abnormal dosimetry results. At a minimum, the radiation protection program policies and procedures for conducting periodic evaluations shall be updated and shall include documentation of the responsible individual(s), evaluation objectives, minimum criteria to consider an evaluation complete, frequency of each evaluation, action to be taken when findings occur, and management and RSC notification of evaluation findings.

2. Within 90 days of completing the assessment pursuant to Section V.D.1, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator, with a written copy of CHH's radiation protection policies and procedures, specifying any revisions made in response to the assessment conducted pursuant to Section V.D.1. Any policies, findings, and related documentation shall be maintained and made available for NRC inspection for a period 3 years following completion of this action.

E. Training Program

1. Within 270 days of the effective date of the Confirmatory Order, CHH shall complete a review of its current radiation protection training program and revise it consistent with the guidance provided in NUREG–1556. Specifically, the review shall assess the sufficiency of training, shall be informed by the results of any periodic assessments of the radiation protection program, and shall establish record-keeping requirements.

2. Within 30 days of completing the review pursuant to Section V.E.1, CHH shall inform the NRC of the completion of the review by sending a letter to the Region I Administrator documenting any planned changes to its training program. The letter shall include a description of the standards used to inform the scope and conduct of the review. CHH shall maintain and make its radiation protection training program, along with associated radiation protection training materials, available to the NRC for inspection for a period of three years after notification to the NRC of the completion of the review.

F. External Communication

1. Within 720 days of the effective date of the Confirmatory Order, CHH shall have conducted the following communications of the importance of ALARA practices with applicable industry clinicians/physician related organizations:

a. CHH shall have attempted at least three times to provide a presentation to a national organization that has a membership comprised of physician authorized users of byproduct material. The presentation shall include a description of the reported exposure received by an AU at CHH including the practice used (*i.e.,* hand in the beam), magnitude of exposure, lessons learned, the importance of adherence to NRC requirements for occupational monitoring, and related corrective actions undertaken by CHH. Within 30 days of completing the presentation, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the presentation materials available to the NRC for review during NRC inspections for three years after the presentation. Presentation materials shall consist of a slide show, at a minimum. If the presentation has not been accepted after three submission attempts by CHH to different national organizations, then CHH shall notify the NRC by sending a letter to the Region I Administrator, including with the letter the rejected presentation proposals, as well as intended presentation materials.

b. CHH shall have attempted at least three times to publish a paper in a journal that has a readership comprised of physician authorized users of byproduct material. The paper shall include a description of the reported exposure received by an AU at CHH including the practice used (*i.e.,* hand in the beam), magnitude of exposure, lessons learned, the importance of adherence to NRC requirements for occupational monitoring, and related corrective actions undertaken by CHH.

Within 30 days of a paper submission attempt, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the paper available to the NRC for review during NRC inspections for three years after the paper is submitted to the journal for review. If the paper has not been accepted for publication after three submission attempts have been made by CHH to different journals, then CHH shall notify the NRC by sending a letter to the Region I Administrator, all with copies of all versions of the paper tendered for publication.

2. As specified below, CHH shall discuss the issues it encountered related to the maintenance of its radiation protection program.

a. Within 720 days of the effective date of the Confirmatory Order, CHH shall have attempted at least three times to provide a presentation describing the issues related to the maintenance of its radiation protection program, resolution of the issues, and the path to compliance to a national organization that has a membership comprised of health physics and radiation professionals. Within 30 days of completing this presentation, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the presentation materials available to the NRC for three years after the presentation for review during NRC inspection. Presentation materials shall consist of a slide show, at a minimum. If the presentation has not been accepted after three submission attempts by CHH to different national organizations, then CHH shall notify the NRC by sending a letter to the Region I Administrator, including with the letter the rejected presentation proposals, as well as intended presentation materials.

b. Within 720 days of the effective date of the Confirmatory Order, CHH shall have attempted at least three times to have a paper published by a national journal that has a readership comprised of health physics and radiation professionals related to the issues related to the maintenance of its radiation protection program, resolution of the issues, and the path to compliance. Within 30 days of a paper submission attempt, CHH shall inform the NRC that the action is complete by sending a letter to the Region I Administrator and shall make the paper available to the NRC during NRC inspections for three years after the paper is submitted to the journal for review. If the paper has not been accepted for publication after three submission attempts have been made by CHH to different journals, then CHH shall notify the NRC by sending a letter to the Region I Administrator, along with copies of all versions of the paper tendered for publication.

This agreement is binding upon successors and assignees of CHH. The Regional Administrator, Region I, may relax or rescind, in writing, any of the above conditions upon demonstration by CHH or its successors of good cause.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Confirmatory Order, other than CHH, may request a hearing within thirty (30) calendar days of the date of issuance of this Confirmatory Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056) and on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10

days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9:00 a.m. and 6:00 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

If a person other than CHH requests a hearing, that person shall set forth with particularity the manner in which their interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of this Confirmatory Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission

Raymond K. Lorson,

Deputy Regional Administrator, NRC Region I.

Dated this 10th day of November 2022

[FR Doc. 2022–28136 Filed 12–23–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–219 and 72–15; NRC–2022–0192]

Holtec Decommissioning International, LLC; Oyster Creek Nuclear Generating Station

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued an exemption in response to an August 2, 2022 request from Holtec Decommissioning International, LLC (HDI) that would permit HDI to investigate and report to the NRC when the Oyster Creek Nuclear Generating Station does not receive notification of receipt of a shipment, or part of a shipment, of low-level radioactive waste within 90 days after transfer, instead of the 20-day investigation requirement currently delineated in the NRC's regulations.

DATES: The exemption was issued on December 15, 2022, and was effective upon issuance.

ADDRESSES: Please refer to Docket ID NRC–2022–0192 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0192. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Marlayna V. Doell, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3178; email: *Marlayna.Doell@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: December 20, 2022.

For the Nuclear Regulatory Commission.

Marlayna V. Doell,

Project Manager, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery and Waste Programs, Office of Nuclear Material Safety and Safeguards.

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

Docket Nos. 50–219 and 72–15

Holtec Decommissioning International, LLC

Oyster Creek Nuclear Generating Station

Exemption from Certain Low-Level Waste Shipment Tracking Requirements of 10 CFR part 20, Appendix G, Section III.E

I. Background.

The decommissioning Oyster Creek Nuclear Generating Station (Oyster Creek) facility consists of a permanently shutdown and defueled boiling-water reactor and a dry cask Independent Spent Fuel Storage Installation (ISFSI) located in the town of Forked River in Ocean County, New Jersey. By letter dated February 14, 2018 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML18045A084), Exelon Generation Company, LLC (Exelon), which was the licensee at the time, submitted certification to the U.S. Nuclear Regulatory Commission (NRC or the Commission) indicating its intention to permanently cease power operations at Oyster Creek pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.82(a)(1)(i).

By letter dated September 25, 2018 (ML18268A258), Exelon certified to the NRC that as of September 17, 2018, operations had ceased at Oyster Creek, and that pursuant to 10 CFR 50.82(a)(1)(ii) all fuel had been removed from the reactor vessel. Effective July 1, 2019, the Oyster Creek Renewed Facility Operating License (RFOL) No. DPR–16, and the general license for the Oyster Creek ISFSI were transferred from Exelon to Oyster Creek Environmental Protection, LLC (OCEP), as the licensed owner and to Holtec Decommissioning International, LLC (HDI), as the licensed decommissioning operator.

Based on the docketing of these certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, as specified in 10 CFR 50.82(a)(2), the renewed facility operating license for Oyster Creek no longer authorizes operation of the reactor or emplacement or retention of fuel in the reactor vessel. The facility is still authorized to possess and store irradiated (*i.e.,* spent) nuclear fuel. Spent fuel is currently stored onsite at the Oyster Creek facility in the ISFSI. By letter dated May 21, 2021 (ML21160A065), HDI certified that all spent nuclear fuel assemblies were permanently transferred out of the Oyster Creek spent fuel pool and placed in storage within the onsite ISFSI.

By letter dated May 21, 2018 (ML18141A775), as supplemented by letter dated September 24, 2018 (ML18267A216), Exelon submitted to the NRC the Post-Shutdown Decommissioning Activities Report (PSDAR), including the site-specific Decommissioning Cost Estimate (DCE), for Oyster Creek, pursuant to 10 CFR 50.82, ''Termination of license.'' The PSDAR outlined the planned decommissioning activities for Oyster Creek, and Exelon selected the SAFSTOR method for decommissioning. By letter dated September 28, 2018 (ML18275A116), HDI submitted to the NRC a revised PSDAR, including a revised site-specific DCE, for Oyster Creek, pursuant to 10 CFR 50.82(a)(7) and contingent upon NRC approval of the proposed license transfer from Exelon to HDI (ML18243A489). HDI selected the DECON method for decommissioning Oyster Creek in the revised PSDAR.

By letter dated December 17, 2018 (ML18241A068), the NRC staff found that the Exelon-submitted SAFSTOR PSDAR, as supplemented, contained the information required by 10 CFR 50.82(a)(4)(i). In that letter, the NRC staff stated that it was treating the HDI-submitted DECON PSDAR as a supplement to the Oyster Creek license transfer application until such time as the NRC made a regulatory decision regarding the license transfer application. On June 20, 2019 (ML19095A454), the NRC staff approved the Oyster Creek license transfer application and the license transfer transaction was consummated on July 1, 2019 (ML19182A342). Accordingly, the NRC staff commenced its review of the HDI-submitted DECON PSDAR under 10 CFR 50.82(a)(4)(i). By letter dated December 5, 2019 (ML19304A079), the NRC staff found that the revised PSDAR contains the information required by 10 CFR 50.82(a)(4)(i) related to the plans for decommissioning the Oyster Creek facility.

In accordance with the revised Oyster Creek PSDAR, by the end of 2035 the licensee is expected to complete all decommissioning work necessary to obtain NRC approval to reduce the Part 50 license site footprint to the ISFSI area only and to allow partial release of the Oyster Creek site for unrestricted future use. Inherent to the plans for this decommissioning process, large volumes of low-level radioactive waste are generated. This low-level radioactive waste requires processing and disposal or only disposal. HDI will transport, by truck or by mixed mode shipments (for example, by a combination of truck and rail), low-level radioactive waste from the facility to locations such as the waste disposal facility operated by Waste Control Specialists (WCS) in Andrews, Texas and the one operated by Energy Solutions in Clive, Utah.

II. Request/Action

By letter dated August 2, 2022 (ML22214A173), HDI requested an exemption from portions of Section III.E of Appendix G, ''Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests,'' to Part 20, ''Standards for Protection Against Radiation,'' of 10 CFR for transfers of low-level radioactive waste from the Oyster Creek facility. Section III.E requires that the shipper of any

low-level radioactive waste to a licensed land disposal or processing facility must investigate and trace the shipment if the shipper has not received notification of the shipment's receipt by the disposal or processing facility within 20 days after transfer. In addition, Section III.E requires licensees to report such investigations to the NRC.

HDI is specifically requesting an exemption from the requirements in 10 CFR part 20, Appendix G, Section III.E, under the provisions of 10 CFR 20.2301, ''Applications for exemptions.'' HDI seeks to extend the 20 day time period for HDI to receive notification that the shipment was received to 90 days after transfer for shipments from the Oyster Creek facility to the intended recipient, before having to investigate and report such shipments to the NRC. HDI's request states that the ability to track the location of all shipments that are in transit will remain in place, regardless of the longer transit times, and are validated daily to monitor for potential diversion of the low-level radioactive waste material. Therefore, this exemption would allow a majority of the shipments to be processed as having arrived on time, while ensuring that HDI will continue to perform an investigation and report excessively long shipments to the NRC in accordance with the intent of 10 CFR part 20, Appendix G.

III. Discussion

A. The Exemption is Authorized by Law

The NRC's regulations in 10 CFR 20.2301 allow the Commission to grant exemptions from the requirements of the regulations in 10 CFR part 20 if it determines the exemption would be authorized by law and would not result in undue hazard to life or property. There are no provisions in the Atomic Energy Act of 1954, as amended (or in any other Federal statute) that impose a requirement to investigate and report on low-level radioactive waste shipments that have not been acknowledged by the recipient within 20 days of transfer. Therefore, the NRC staff concludes that there is no statutory prohibition on the issuance of the requested exemption and the NRC is authorized to grant the exemption by law.

B. The Exemption Presents no Undue Hazard to Life and Property

The purpose of 10 CFR part 20, Appendix G, Section III.E is to require licensees to investigate, trace, and report radioactive shipments that have not reached their destination, as scheduled, for unknown reasons. HDI states that ''between December 2019 and February 2021, Oyster Creek shipped thirty-eight railcars worth of low-level radioactive waste to the WCS disposal facility in Andrews, Texas. The total transit time when the shipments were released from the Oyster Creek facility until verification of receipt, varied from thirty (30) to one hundred thirty-four (134) days.'' HDI's experience at Oyster Creek demonstrates that rail and mixed mode shipments from Oyster Creek to these facilities can routinely take longer than 20 days for various reasons that cannot be anticipated nor avoided. Based on these past reports and experiences, the NRC staff concludes that delays due to rail scheduling are likely to recur.

Further, HDI notes that the requested exemption is similar to the ones previously approved by the NRC, namely: San Onofre Nuclear Generating Station on November 13, 2020 (ref. ML20287A358), Fort Calhoun Station on June 30, 2020 (ref. ML20162A155), Vermont Yankee Nuclear Power Station on February 5, 2020 (ref. ML20017A069), La Crosse Boiling Water Reactor facility on May 2, 2017 (ref. ML17124A210), and Zion Nuclear Power Station, Units 1 and 2, on January 30, 2015 (ref ML15008A417). The NRC staff reviewed these other exemption requests and notes that all of the facilities listed above are reactor facilities undergoing decommissioning. The NRC staff agrees that these exemption requests are similar to the exemption requested by HDI.

The NRC staff also notes that HDI is in the process of decommissioning Oyster Creek. During reactor decommissioning, large volumes of slightly contaminated debris are generated and require disposal. Disposal of Oyster Creek's low-level radioactive waste will require mixed mode (truck to rail to truck) shipments to waste disposal facilities or processors. Oyster Creek does not have direct rail access onsite and currently utilizes road shipments to intermodal transfer terminals for transfer of containers onto rail as the primary transport method. This transport method has the added benefit to reduce overall highway miles traveled. As decommissioning continues, an increase in truck to rail shipments is expected.

As explained by HDI, HDI takes actions during the preparation of shipments of low-level radioactive waste from Oyster Creek to predict and mitigate undesirable conditions as much as possible, but unanticipated delays can often extend the shipping duration beyond the requisite 20 days. Due to the complex scheduling and congestion on the planned rail systems, delays beyond the estimated durations are often encountered after the waste leaves site. Rail shipments may sit at a remote railyard waiting for clearance to depart or for maintenance of a railcar in need of repair; either of which creates delays that can extend the estimated shipping durations from Oyster Creek and are outside of the shipper's (*i.e.,* HDI's) control. Administrative processes at the disposal facility and mail delivery times can add several additional days before notification of receipt is available. HDI states that exceeding the 20-day shipment duration results in an administrative burden as a result of the required investigations and reporting, even though shipments continue to be under requisite controls.

According to HDI, low-level radioactive waste shipments from the Oyster Creek facility can take longer than 20 days to reach a waste disposal facility; however, the delay is not the result of loss, but a consequence of the complexity involved in shipping large components. In addition, the NRC staff is aware of shipping industry practices that could result in shipping durations exceeding 20 days due to issues not specifically related to the transport of large components, such as rail cars containing low-level radioactive waste waiting in switchyards to be included in a complete train to the disposal facility.

In addition, in terms of potential effects on a member of the public, the primary cause of low-level radioactive waste shipment delays is coordination with the rail carriers. When these delays happen, the shipment is generally within a railyard and not near a member of the public or a public place. The only way a low-level radioactive waste shipment would remain in a public place for an unusual amount of time is if there was a problem with the transport vehicle or the rail system itself. In that instance, the NRC staff notes that all low-level radioactive waste shipments from Oyster Creek are required to be compliant with the U.S. Department of Transportation (DOT) and NRC requirements for transportation of low-level radioactive packaging, placarding, and allowable radiation levels at the surface of the package for health and safety purposes during transit, including during switchyard staging. Furthermore, the shipments are required to be under control of the shipper at all times, tracked by the licensee, and periodically monitored by the licensee, as needed. Therefore, there are no potential health and safety concerns associated with this material sitting in a switchyard for an extended period of time. In the unlikely event that a low-level waste shipment were to remain in a public place for an

extended period of time, adherence to the DOT transportation requirements would also ensure that there would be no health and safety concerns regarding potential dose to the public.

Based on the history of low-level radioactive waste shipments from Oyster Creek and the lack of potential health and safety concerns associated with this material sitting in a switchyard for extended period of time, the need to investigate, trace, and report on low-level radioactive waste shipments that take longer than 90 days is therefore appropriate.

As indicated in the request for exemption, for rail and truck shipments from Oyster Creek, HDI will use a tracking system that allows daily monitoring of a shipments' progress to its destination and the Oyster Creek shipping procedures prescribe the expectations for tracking and communications during transit. The NRC staff believes these steps will allow for monitoring the progress of the shipments by the rail or truck carrier on a daily basis, if needed, in lieu of the 20-day requirement and will initiate an investigation as provided for in Section III.E of Appendix G to 10 CFR part 20 after 90 days. Because of the oversight and ability to monitor low-level radioactive waste shipments throughout the entire journey from Oyster Creek to a disposal or processing site as noted above, the NRC staff concludes that it is unlikely that a shipment could be lost, misdirected, or diverted without the knowledge of the carrier or HDI and there is no potential health and safety concern presented by the requested exemption. Furthermore, by extending the elapsed time for receipt acknowledgment to 90 days before requiring investigations, tracing, and reporting, a reasonable upper limit on shipment duration is maintained if a breakdown of normal tracking systems were to occur.

Consequently, the NRC staff finds that extending the receipt of notification period from 20 to 90 days after transfer of the low-level radioactive waste as described by HDI in its August 2, 2022, letter would not result in an undue hazard to life or property.

C. The Exemption is Subject to a Categorical Exclusion

With respect to compliance with Section 102(2) of the National Environmental Policy Act, 42 U.S.C. 4332(2) (NEPA), the NRC staff has determined that the proposed action, the approval of the HDI exemption request, is within the scope of the categorical exclusion listed at 10 CFR 51.22(c)(25). The proposed action presents (i) no significant hazards considerations; (ii) would not result in a significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) would not result in a significant increase in individual or cumulative public or occupational radiation exposure; (iv) has no significant construction impact; (v) does not present a significant increase in the potential for or consequences from radiological accidents. The requirements from which an exemption is sought involves reporting requirements under 10 CFR 51.22(c)(25)(vi)(B) as well as inspection or surveillance requirements under 10 CFR 51.22(c)(25)(vi)(C). Given the applicability of relevant categorical exclusions, no further analysis is required under NEPA.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 20.2301, the exemption is authorized by law and will not result in undue hazard to life or property. Therefore, effective immediately, the Commission hereby grants HDI an exemption from 10 CFR part 20, Appendix G, Section III.E to extend the receipt of notification period from 20 days to 90 days after transfer of low-level radioactive waste shipments from the Oyster Creek Nuclear Generating Station facility to a licensed land disposal or processing facility.

Dated this 15th day of December, 2022
For the Nuclear Regulatory Commission.
Jane E. Marshall, Director,
Division of Decommissioning, Uranium Recovery, and Waste Programs,
Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2022–28115 Filed 12–23–22; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023–94 and CP2023–95]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 28, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633,

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2023–94 and CP2023–95; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 80 to Competitive Product List and Notice of Filing Materials Filed Under Seal; *Filing Acceptance Date:* December 19, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* December 28, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022–28097 Filed 12–23–22; 8:45 am]

BILLING CODE 7710–FW–P

RAILROAD RETIREMENT BOARD

Civil Monetary Penalty Inflation Adjustment

AGENCY: Railroad Retirement Board.

ACTION: Notice announcing updated penalty inflation adjustments for civil monetary penalties for 2023.

SUMMARY: As required by the Bipartisan Budget Act of 2015, entitled the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, the Railroad Retirement Board (Board) hereby publishes its 2023 annual adjustment of civil penalties for inflation.

FOR FURTHER INFORMATION CONTACT: Peter J. Orlowicz, Senior Counsel, Railroad Retirement Board, 844 North Rush Street, Chicago, IL 60611–1275, (312) 751–4922, TTD (312) 751–4701.

SUPPLEMENTARY INFORMATION: Section 701 of the Bipartisan Budget Act of 2015, Public Law 114–74 (Nov. 2, 2015), entitled the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note) (Inflation Adjustment Act) to require agencies to publish regulations adjusting the amount of civil monetary penalties provided by law within the jurisdiction of the agency not later than January 15th of every year.

For the 2023 annual adjustment for inflation of the maximum civil penalty under the Program Fraud Civil Remedies Act of 1986, the Board applies the formula provided by the 2015 Act and the Board's regulations at title 20, Code of Federal Regulations, part 356. In accordance with the 2015 Act, the amount of the adjustment is based on the percent increase between the Consumer Price Index (CPI–U) for the month of October preceding the date of the adjustment and the CPI–U for the October one year prior to the October immediately preceding the date of the adjustment. If there is no increase, there is no adjustment of civil penalties. The percent increase between the CPI–U for October 2022 and October 2023, as provided by Office of Management and Budget Memorandum M–23–05 (December 15, 2022) is 1.07745 percent. Therefore, the new maximum penalty under the Program Fraud Civil Remedies Act is $13,508 (the 2022 maximum penalty of $12,537 multiplied by 1.07745, rounded to the nearest dollar). The new minimum penalty under the False Claims Act is $13,508 (the 2022 minimum penalty of $12,537 multiplied by 1.07745, rounded to the nearest dollar), and the new maximum penalty is $27,018 (the 2022 maximum penalty of $25,076 multiplied by 1.07745, rounded to the nearest dollar). The adjustments in penalties will be effective December 27, 2022.

Dated: December 21, 2022.

By Authority of the Board.

Stephanie Hillyard,

Secretary to the Board.

[FR Doc. 2022–28113 Filed 12–23–22; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96546; File No. SR–PEARL–2022–59]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule To Establish a Monthly Membership Fee

December 20, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 9, 2022 MIAX PEARL, LLC (''MIAX Pearl'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a 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 is filing to amend the fee schedule (the ''Fee Schedule'') applicable to MIAX Pearl Equities, an equities trading facility of the Exchange.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl,* at MIAX Pearl's principal office, 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 establish a $200 monthly Membership Fee for Equity Members of the Exchange. The Exchange proposes to assess the monthly Membership Fee to each active Equity Member at the close of business on the first day of each month. The Exchange proposes to specify within the Fee Schedule that an active membership means any month the Equity Member is certified in the membership system and the Equity Member is credentialed to use one or more ports in the production environment. For example, the monthly Membership Fee for January 2023 will be assessed to all active Equity Members at the close of business on January 2, 2023, the first business day of the month. This filing and the proposed fee amount ($200 per month per Equity Member) are identical to a recent monthly Membership fee adopted by MEMX, LLC (''MEMX''). The Exchange is not proposing anything different than what was adopted in the MEMX filing.

The Exchange also proposes that if an Equity Member is pending a voluntary termination of rights as a Member pursuant to Exchange Rule 206 prior to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the time any monthly Membership Fee will be assessed (*i.e.,* the close of business on January 2, 2023), and the Equity Member does not utilize the facilities of the Exchange while such voluntary termination of rights is pending, then the Equity Member will not be obligated to pay the monthly Membership Fee, as such Member will not be considered to have an ''active'' membership. The Exchange believes this to be appropriate because there are several pre-conditions before a voluntary resignation shall take effect pursuant to Exchange Rule 206. This is also similar to the MEMX filing to adopt the MEMX monthly Membership fee.

As proposed, the monthly Membership Fee for an Equity Member will not be pro-rated, which the Exchange believes is reasonable based on the frequency that the proposed fee would be assessed (*i.e.,* monthly instead of applying to a longer period) and the relatively low proposed fee amount of $200 for the monthly Membership Fee. This is also similar to the MEMX filing to adopt the MEMX monthly Membership fee. The Exchange does not presently contemplate proposing any application fees, trading rights or trading permit fees, market participant identifier (''MPID'') fees or so-called ''headcount'' fees. The Exchange further notes that it is separately filing a proposal to amend fees for physical connectivity and ports (with the same implementation date as the proposed changes in this filing).

The Exchange proposes to establish the monthly Membership fee as Section 4), Membership Fees, and move current Section 4), Additional Fees, to new Section 5 in the Fee Schedule.

Implementation Date

The Exchange proposes to implement the proposed Membership Fee beginning January 1, 2023.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of 6 of the Act,[3] in general, and with s 6(b)(4) and 6(b)(5) of the Act,[4] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Equity Members and other persons using its facilities and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that there is value in becoming an Equity Member of the Exchange and that the proposed monthly Membership Fee is reasonable. The proposed monthly Membership Fee is identical in amount and the way the Exchange proposes to assess it as the monthly Membership fee recently adopted by MEMX.[5] The proposed monthly Membership fee is also lower than or comparable to the membership fees imposed by several other national securities exchanges that charge such fees.[6] Moreover, insofar as the Exchange does not charge—nor does it presently contemplate charging—application fees, trading rights fees, trading permit fees, or fees for multiple MPIDs, the comparative price of membership is less or significantly less than comparative prices at other exchanges. The Exchange also does not charge—nor does it presently contemplate charging—so-called ''headcount fees,'' *e.g.,* fees charged for each Form U–4 filed for registration of a representative or a principal or the transfer or re-licensing of such personnel,[7] further highlighting the reasonableness of the proposed monthly Membership Fee.

The Exchange believes that the proposed monthly Membership Fee is not unfairly discriminatory because it would be assessed equally across all Equity Members or firms that seek to become Equity Members. The Exchange believes that the proposed monthly Membership Fee is not unfairly discriminatory because no broker-dealer is required to become a member of the Exchange. Instead, many market participants awaited the Exchange growing to a certain percentage of market share before they would join as an Equity Member of the Exchange. In addition, many market participants still have not joined the Exchange despite the Exchange's growth in one year to more than 1% of the overall equities market share. To illustrate, the Exchange currently has 49 Equity Members.[8] However, based on publicly available information regarding a sample of the Exchange's competitors, MEMX has 66 members, NYSE has 142 members, Cboe BZX has 140 members, and Investors Exchange LLC (''IEX'') has 133 members.[9]

Accordingly, the vigorous competition among national securities exchanges provides many alternatives for firms to voluntarily decide whether membership to the Exchange is appropriate and worthwhile, and no broker-dealer is required to become a member of the Exchange. Specifically, neither the trade-through requirements under Regulation NMS nor broker-dealers' best execution obligations require a broker-dealer to become a member of every exchange. The Exchange acknowledges that competitive forces may require certain broker-dealers to be members of all equities exchanges. However, the Exchange believes that the proposed fee of $200 as a monthly Membership Fee is reasonable, equitably allocated and not unfairly discriminatory, even for a broker-dealer that deemed it necessary to join the Exchange for business purposes, as those business reasons should presumably result in revenue capable of covering the proposed fee.

The Exchange further believes that the proposed fee would be an equitable allocation of reasonable dues, fees, and other charges among its Equity Members and issuers and other persons using its facilities, and are not unfairly discriminatory. As the Commission noted in its Concept Release Concerning Self-Regulation:

The Commission to date has not issued detailed rules specifying proper funding levels of [self-regulatory organization (''SRO'')] regulatory programs, or how costs should be allocated among the various SRO constituencies. Rather, the Commission has

[3] 15 U.S.C. 78f.

[4] 15 U.S.C. 78f(b)(4) and (5).

[5] *See supra* note 4 [sic].

[6] *See, e.g.,* the New York Stock Exchange LLC (''NYSE'') annual trading license fee for member organizations ranges from approximately $2,080 per month to $4,165 per month based on the type of member organization and number of trading licenses. *See* NYSE Price List 2022, Trading Licenses, page 23, *available at: https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf* (last visited December 6, 2022). The Nasdaq Stock Market LLC (''Nasdaq'') annual membership fee is $3,000 plus a monthly $1,250 trading rights fee (together with the annual membership fee, totaling $18,000 per year). *See* ''NASDAQ Membership Fees,'' Nasdaq Price List, *available at: http://nasdaqtrader.com/Trader.aspx?id=PriceListTrading2#membership* (last visited December 6, 2022). *See also* Securities Exchange Act Release No. 81133 (July 12, 2017), 82 FR 32904 (July 18, 2017) (SR–NASDAQ–2017–065) (discussing the reasonableness of Nasdaq's fees). Finally, Cboe BZX Exchange, Inc. (''Cboe BZX'') charges an annual membership fee of $2,500 plus an additional fee of $350 per month for each additional MPID a member maintains other than their first (*i.e.,* an annual fee of $4,200 per additional MPID). *See* ''Membership Fees'' and ''Market Participant Identifier ('MPID') Fees'' sections of the Cboe BZX Fee Schedule, *available at:* Cboe BZX Fee Schedule (last visited December 6, 2022).

[7] *See, e.g.,* ''NASDAQ Membership Fees,'' *supra* note 11 [sic] ($55 for each Form U–4 filed for the registration of a Representative or Principal, and $55 for each Form U–4 filed for the transfer or re-licensing of a Representative or Principal).

[8] *See* MIAX Pearl Equities Exchange Member Directory, *available at https://www.miaxoptions.com/sites/default/files/page-files/MIAX_Pearl_Equities_Exchange_Members_11012022.pdf* (last visited December 6, 2022).

[9] *See supra* note 4 [sic]; *see also* NYSE Membership Directory, *available at: https://www.nyse.com/markets/nyse/membership;* Cboe BZX Form 1 filed November 19, 2021, *available at: https://www.sec.gov/Archives/edgar/vprr/2100/21009368.pdf;* IEX Current Members list, *available at: https://exchange.iex.io/resources/trading/current-* membership/.

examined the SROs to determine whether they are complying with their statutory responsibilities. This approach was developed in response to the diverse characteristics and roles of the various SROs and the markets they operate. The mechanics of SRO funding, including the amount of revenue that is spent on regulation and how that amount is allocated among various regulatory operations, is related to the type of market that an SRO is operating. Thus, each SRO and its financial structure is, to a certain extent, unique. While this uniqueness can result in different levels of SRO funding across markets, it also is a reflection of one of the primary underpinnings of the National Market System. Specifically, by fostering an environment in which diverse markets with diverse business models compete within a unified National Market System, investors and market participants benefit.[10]

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of s 6(b)(4) and 6(b)(5) of the Act [11] in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Equity Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. Effective regulation is central to the proper functioning of the securities markets. Recognizing the importance of such efforts, Congress decided to require national securities exchanges to register with the Commission as self-regulatory organizations to carry out the purposes of the Act. The Exchange therefore believes that it is critical to ensure that regulation is appropriately funded. The monthly Membership Fee is expected to provide a source of funding towards the Exchange's costs related to onboarding Equity Members and providing ongoing support.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with 6(b)(8) of the Act,[12] the Exchange believes that the proposed rule change would not impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange's proposed Membership Fee will be lower than the cost of membership on other exchanges,[13] and therefore, may stimulate intramarket [sic] competition by attracting additional firms to become Equity Members on the Exchange or at least should not deter interested participants from joining the Exchange. In addition, membership fees are subject to competition from other exchanges. Accordingly, if the changes proposed herein are unattractive to market participants, it is likely the Exchange will see a decline in membership as a result.

The Exchange believes that the proposed fee change will not impact intermarket [sic] competition because it will apply to all Equity Members equally. The Exchange operates in a highly competitive market in which market participants can determine whether or not to join the Exchange based on the value received compared to the cost of joining and maintaining membership on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were 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 19(b)(3)(A)(ii) of the Act,[14] and Rule 19b–4(f)(2) [15] 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 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–PEARL–2022–59 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–PEARL–2022–59. 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–PEARL–2022–59 and should be submitted on or before January 17, 2023. For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

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[10] *See* Securities Exchange Act Release No. 50700 (November 22, 2004), 69 FR 71255, 71267–68 (December 8, 2004) (File No. S7–40–04).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] 15 U.S.C. 78f(b)(8).

[13] *See supra* note 11 [sic].

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 240.19b–4(f)(2).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96553; File No. SR–PEARL–2022–60]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To No Longer Operate Its 10 Gigabit Ultra-Low Latency Connectivity on a Single Shared Network With Its Affiliate, Miami International Securities Exchange, LLC

December 20, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 19, 2022, MIAX PEARL, LLC (''MIAX Pearl'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a 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 is filing a proposal to no longer operate 10 gigabit (''Gb'') ultra-low latency (''ULL'') connectivity to the Exchange on a single shared network with its affiliate, Miami International Securities Exchange, LLC (''MIAX''), due to ever-increasing capacity constraints and to accommodate anticipated access needs for Members [3] and other market participants.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX Pearl's principal office, 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 no longer operate 10Gb ULL connectivity to the Exchange on a single shared network with its affiliate, MIAX, due to ever-increasing capacity constraints and to accommodate anticipated access needs for Members and other market participants. The Exchange has shared a single network with MIAX since MIAX Pearl became operational on February 6, 2017.[4] On the contrary, the Exchange and its other affiliate, MIAX Emerald, LLC (''MIAX Emerald''), operate on separate, unshared 10Gb ULL networks, since the launch of MIAX Emerald in March 2019.[5] The Exchange believes this separated network structure is also similar to at least one other national securities exchange group with multiple exchanges.[6] Operating two separate national securities exchanges on a single shared network provided certain benefits, such as streamlined connectivity to multiple exchanges, and simplified exchange infrastructure. However, doing so is no longer sustainable due to ever-increasing capacity constraints and current System [7] limitations. The network is not an unlimited resource. As described more fully below, the connectivity needs of Members and market participants increased every year since the launch of the Exchange and the operations of the Exchange and MIAX on a single shared 10Gb ULL network is no longer feasible. This requires constant System expansion to meet Member demand for additional ports and 10Gb ULL connections, which has resulted in limited available System headroom (described in detail below). Therefore, the Exchange proposes to provide 10Gb ULL connectivity to the Exchange and MIAX on separate networks so that the Exchange and MIAX may increase their respective System capacities to meet the ongoing and anticipated connectivity needs of Members, prospective Members, and other market participants.

The Exchange began to operate on a single shared network with MIAX when the Exchange commenced operations as a national securities exchange on February 7, 2017.[8] The Exchange and MIAX have operated on a single shared network to provide Members with a single convenient set of access points for both exchanges. Both the Exchange and MIAX offer two methods of connectivity, 1Gb and 10Gb ULL connections. The 1Gb connection services are supported by a discrete set of switches providing 1Gb access ports to Members. The 10Gb ULL connection services are supported by a second and mutually exclusive set of switches providing 10Gb ULL access ports to Members. Today, both the 1Gb and 10Gb ULL shared extranet ports allow Members to use one connection to access both exchanges, namely their trading platforms, market data systems, test systems, and disaster recovery facilities.

As stated above, the shared network is not an unlimited resource and its expansion is constrained by MIAX Pearl's and MIAX's ability to provide fair and equitable access to all market participants of both markets. The Exchange and MIAX continue to be able to meet the access demands of new subscribers and satisfy the ongoing access demands of existing subscribers. However, over time, due to the ever-increasing connectivity demands, the Exchange now finds it necessary to bifurcate 10Gb ULL connectivity to the Exchange's and MIAX's Systems and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of these Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] *See* Press Release ''MIAX PEARL Successfully Launches Trading Operations'' (February 7, 2017), *available at https://www.miaxoptions.com/press-releases?_miax_filter_created%5Bmin%5D=2017-02-01+00%3A00%3A00&_miax_filter_created%5Bmax%5D=2017-02-28+23%3A59%3A59&actions=&_miax_filter_month=2&_miax_filter_year=2017; see also* Securities Exchange Act Release No. 79543 (December 13, 2016), 81 FR 92901 (December 20, 2016) (File No. 10–227) (order approving application of MIAX PEARL, LLC for registration as a national securities exchange).

[5] *See* Securities Exchange Act Release No. 87877 (December 31, 2019), 85 FR 738 (January 7, 2020) (SR–EMERALD–2019–39) (proposal to adopt connectivity fees without providing access to MIAX Emerald's affiliates, MIAX and MIAX Pearl, via a single shared connection).

[6] *See* the Physical Connectivity Fees sections of the Cboe BYX Exchange, Inc. (''BYX''), Cboe BZX Exchange, Inc. (''BYX''), Cboe EDGA Exchange, Inc. (''EDGA''), and Cboe EDGX Exchange, Inc. (''EDGX'', collectively with BYX, BZX, and EDGA, the ''Cboe Equity Exchanges'') equity fee schedules (not providing that a single port provides connectivity to each of Cboe Equity Exchanges).

[7] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[8] *See* Securities Exchange Act Release No. 80061 (February 17, 2017), 82 FR 11676 (February 24, 2017) (establishing MIAX Pearl Fee Schedule and establishing that the MENI can also be configured to provide network connectivity to the trading platforms, market data systems, test systems, and disaster recovery facility of the MIAX Pearl's affiliate, MIAX, via a single, shared connection).

networks to be able to continue to meet ongoing and future 10Gb ULL connectivity and access demands. Currently, the Exchange maintains sufficient headroom to meet ongoing and future requests for 1Gb connectivity. Therefore, the Exchange does not propose to alter 1Gb connectivity and will continue to provide 1Gb connectivity over a shared network and provide access to both the Exchange and MIAX over a single 1Gb connection.

The Exchange has two categories of Members: Market Makers [9] and Electronic Exchange Members [10] (''EEMs''). 10Gb ULL connectivity is predominantly used by Market Makers, latency sensitive liquidity removers, or those that require higher throughput (*i.e.,* greater than 1Gb). 1Gb connectivity is predominately used by EEMs who are less latency sensitive and tend to utilize a limited number of 1Gb connections. These EEMs will continue to be able to use that single 1Gb connection to access both the Exchange and MIAX. Certain EEMs use 10Gb ULL connectivity, primarily where that EEM also acts as a Market Maker either on the Exchange and/or MIAX and leverages that 10Gb ULL connection to access both exchanges. Service bureaus [11] also purchase 10Gb ULL connectivity and resell that connectivity to market participants who may not have direct connectivity to the Exchange.

Unlike the switches that provide 1Gb connectivity, the switches that provide 10Gb ULL connectivity have experienced a significant decrease in the availability for additional 10Gb ULL connections on each switch. This is mostly driven by the connectivity demands of latency sensitive Members (*e.g.,* Market Makers and liquidity removers) that seek to maintain connectivity across multiple 10Gb ULL switches. Such Members do not typically use a shared 10Gb ULL connection to reach both the Exchange and MIAX due to related latency concerns. Instead, those Members maintain dedicated separate 10Gb ULL connections for the Exchange and separate dedicated 10Gb ULL connections for MIAX. This results in a much higher 10Gb ULL usage per switch by those Members on the existing shared 10Gb ULL network than would otherwise be needed if the Exchange and MIAX had their own dedicated 10Gb ULL networks, similar to that provided by other exchanges, including the Exchange's and MIAX's affiliate, MIAX Emerald. Separation of the Exchange and MIAX 10Gb ULL networks would naturally lend itself to reduced 10Gb ULL port consumption on each switch and, therefore, increased 10Gb ULL port availability for current Members and new Members.

To date, the Exchange and MIAX have continued to add switches to meet ongoing demand for 10Gb ULL connectivity. Unfortunately, that is no longer sustainable because simply adding additional switches to expand the current shared 10Gb ULL network would not continue to alleviate the issue of limited available port connectivity. While it would result in a gain in overall port availability, the existing switches in use would continue to suffer from lack of port headroom given many latency sensitive Members' needs for a presence on each switch to reach both the Exchange and MIAX. This is because those latency sensitive Members seek to have a presence on each switch to maximize the probability of experiencing the best network performance. Those Members routinely decide to rebalance the amount of orders and/or messages over its various connections to ensure each connection is operating with maximum efficiency. Simply adding switches to the extranet is ineffective at resolving the port availability concerns on the existing extranet since many of the latency sensitive Members are unwilling to relocate their connections to a new switch due to the potential detrimental performance impact. As such, the impact of adding new switches and rebalancing ports is not effective. The Exchange has, therefore, found that ongoing and continued rebalancing once additional switches are added has had, and will continue to have, a diminishing return on increasing available 10Gb ULL connectivity.

The below example illustrates how the bifurcation of the 10Gb ULL network would lead to expanded access. This example is for illustrative purposes only. Assume the shared network includes ten (10) switches and each switch provides access via 24 10Gb ULL connections. For each switch, the numerator represents the number of consumed 10Gb ULL connections while the denominator represents the number of available 10Gb ULL connections. The ''Shared Network'' row illustrates the number of consumed and available 10Gb ULL connections on each switch. The usage of the ports on the shared network are roughly distributed 50% to MIAX Options and 50% to MIAX Pearl Options. The ''Single MIAX Network'' and ''Single Pearl Network'' rows illustrate how the Exchange may double its available 10Gb ULL connections simply by bifurcating the Shared 10Gb ULL network.

Switch	1	2	3	4	5	6	7	8	9	10
Shared Network	18/6	19/5	16/8	17/7	20/4	16/8	15/9	17/7	13/11	14/10
Single MIAX Network	9/15	9/15	8/16	8/16	10/14	8/16	7/17	8/16	6/18	7/17
Single Pearl Network	9/15	10/14	8/16	9/15	10/14	8/16	8/16	9/15	7/17	7/17

Based on its experience and expertise, the Exchange finds the most practical way to increase connectivity availability on its switches is to bifurcate the existing 10Gb ULL networks for the Exchange and MIAX by migrating the exchange's connections from the shared network onto their own set of switches. If a number of new Members seek to participate in high frequency activity and require a port on each switch, they could quickly consume the available ports on the shared extranet. Further, if an existing Member seeks to temporarily double their port connections while they transition to new network and/or server infrastructure, they could consume the remaining available ports on the shared extranet. The Exchange, therefore, believes it is necessary and most efficient to bifurcate the Exchange

[9] The term ''Market Maker'' or ''MM'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of these Rules. *See* Exchange Rule 100.

[10] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[11] Service bureaus provide access to market participants to submit and execute orders on an exchange. On the Exchange, a Service Bureau may be a Member. Some Members utilize a Service Bureau for connectivity and that Service Bureau may not be a Member. Some market participants utilize a Service Bureau who is a Member to submit orders. Only Members may submit orders or quotes through 10Gb ULL connectivity.

and MIAX 10Gb ULL networks so that both exchanges can continue to satisfy ongoing and anticipated future requests for additional connectivity allowing it to provide meaningful and fair access to each market.

Bifurcating the Exchange and MIAX 10Gb ULL networks provides benefits beyond the ability to continue to meet ongoing and anticipated connectivity demands. For example, today if there is a problem on the shared network, it could impact the operation of both the Exchange and MIAX. As national securities exchanges, the Exchange and MIAX are subject to Regulation Systems Compliance and Integrity (''Reg. SCI'').[12] Reg. SCI Rule 1001(a) requires that the Exchange and MIAX establish, maintain, and enforce written policies and procedures reasonably designed to ensure (among other things) that their Reg. SCI systems have levels of capacity adequate to maintain the Exchange's and MIAX's operational capabilities and promote the maintenance of fair and orderly markets.[13] By separating the 10Gb ULL networks, any potential system issue would be limited to one exchange, narrowing the impact and preventing unnecessary systems disruptions on the other exchange. Bifurcating the networks supports the Reg. SCI obligations for MIAX Pearl and MIAX in this regard by limiting any potential future risk of a systems issue to one exchange and not impacting the operations or market participants of the other exchange. Bifurcating the networks also allows each exchange to evolve separately, potentially by using different technology to cater to the unique demands of each exchange and their market participants to meet future needs.

The Exchange again notes that operating affiliated exchanges' over separate networks is not new or novel. For example, the Exchange's affiliate, MIAX Emerald, currently operates on a separate network.[14] The Exchange notes that at least one other group of affiliated exchanges operate on separate networks.[15]

The Exchange will file a separate proposal with the Commission pursuant to Section 19(b)(3)(A)(ii) of the Act[16] to: (i) Set forth the applicable fees for the bifurcated 10Gb ULL network; (ii) remove provisions in the Exchange fee schedule that provides for a shared 10Gb ULL network; and (iii) specify that only the 1Gb network connection will continue to be shared by both the Exchange and MIAX. The Exchange will not bifurcate the 10Gb ULL network until it files a proposal to set forth the applicable fees for immediate effectiveness pursuant to Section 19(b)(3)(A)(ii) of the Act.[17]

Implementation

Due to the technological changes associated with this proposed change, the Exchange expects to bifurcate the Exchange and MIAX networks in the first quarter of 2023, currently anticipated to be January 23, 2023. The Exchange issued a Trading Alert on August 12, 2022 publicly announcing the planned network change and implementation plan and dates to provide market participants adequate time to prepare.[18] Any changes to the January 23, 2023 implementation date would be announced in a separate alert.

2. Statutory Basis

The Exchange believes that its proposal to bifurcate 10Gb ULL connectivity in the System networks for the Exchange and MIAX are consistent with Section 6(b) of the Act[19] in general, and furthers the objectives of Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that its proposal is consistent with the requirements under Section 6(b)(5)[20] of the Act that the Exchange's proposed changes remove impediments to and perfect the mechanism of a free and open market and a national market system. Operating affiliated exchanges on their own dedicated, separate networks is not new or novel. The Exchange notes that it and its affiliate, MIAX Emerald, currently operate on separate networks.[21] The Exchange is also aware of at least on other group of affiliated exchanges also operate on separate networks.[22]

The Exchange began to operate on a single shared network with MIAX when MIAX Pearl commenced operations as a national securities exchange on February 7, 2017.[23] This shared network is not an unlimited resource and its expansion is constrained by its ability to provide fair and equitable access to all market participants. Due to the ever-increasing connectivity demands, the Exchange finds it necessary to bifurcate 10Gb ULL connectivity to the Exchange's and MIAX's Systems and networks to be able to continue to meet ongoing and future 10Gb ULL connectivity and access demands. Unlike switches for 1Gb connectivity, switches dedicated to 10Gb ULL connectivity have experienced a significant decrease in port headroom mostly driven by connectivity demands of latency sensitive Members that seek to maintain connectivity across multiple 10Gb ULL switches. Separation of the 10Gb ULL networks of the Exchange and MIAX would naturally lend itself to reduced port consumption and, therefore, increased port availability, allowing the Exchange to continue to meet ongoing and anticipated requests for 10Gb ULL connectivity. Therefore, the Exchange believes this proposal removes impediments to and perfects the mechanism of a free and open market and a national market system.

Further, the proposed changes will allow the Exchange and MIAX to adjust the connectivity and access to their Systems in order to ensure that both markets are able to provide consistent and fair access to their Members on non-discriminatory terms and ensure sufficient capacity and headroom in their Systems. The Exchange and MIAX constantly monitor their Systems' performance based on market conditions and the potential need to make adjustments based on customer demand. Accordingly, the Exchange's obligations under Section 6(b)(5) of the Act,[24] market participant demand, and market conditions are key drivers of the System's architecture and expansion and, thus, the Exchange believes simply adding more switches and not bifurcating the 10Gb ULL networks is not an appropriate mechanism to provide fair and open access to the Exchange and MIAX.

[12] 17 CFR 242.1000–1007.

[13] 17 CFR 242.1001(a).

[14] *See supra* note 5.

[15] *See supra* note 6.

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

[17] *Id.*

[18] *See MIAX Options and MIAX Pearl Options—Announce planned network changes related to shared 10G ULL extranet,* issued August 12, 2022, *available at https://www.miaxoptions.com/alerts/2022/08/12/miax-options-and-miax-pearl-options-announce-planned-network-changes-related-0* (last visited November 17, 2022).

[19] 15 U.S.C. 78f(b).

[20] *Id.*

[21] *See supra* note 5.

[22] *See supra* note 6.

[23] *See* Securities Exchange Act Release No. 80061 (February 17, 2017), 82 FR 11676 (February 24, 2017) (establishing MIAX Pearl Fee Schedule and establishing that the MENI can also be configured to provide network connectivity to the trading platforms, market data systems, test systems, and disaster recovery facility of the MIAX Pearl's affiliate, MIAX, via a single, shared connection).

[24] *See* 15 U.S.C. 78f(b).

The Exchange and MIAX anticipate that they will continue to expand their Systems and provide Members and other market participants with additional access based on customer demand and in response to changing market conditions. The Exchange represents that any expansion or adjustments in the number of available switches for network access will be conducted in a similar manner that ensures fair access to its System. The Exchange will also continuously assess its connectivity options and availability to ensure that they meet the needs of all market participants seeking to access the Exchange and MIAX.

The Exchange believes that its proposal is consistent with the requirements under Section 6(b)(5) of the Exchange Act that the Exchange provide access on terms that are not unfairly discriminatory and that the rules of an Exchange promote just and equitable principles of trade.[25] The Exchange believes the proposed changes promote just and equitable principles of trade because the proposal to split the Exchange's and MIAX's shared 10Gb ULL network connectivity will apply equally to all market participants and Members of both exchanges. The proposed bifurcation of the Exchange and MIAX 10Gb ULL network connectivity will promote just and equitable principles of trade because it will allow the Exchange and MIAX to be able to continue to offer access to their Systems on terms that are not unfairly discriminatory by continuing to meeting ongoing and anticipated connectivity demands of all Members. The shared 10Gb ULL network is not an unlimited resource of either MIAX Pearl or MIAX and its expansion is constrained by its ability to provide fair and equitable access to all market participants. The Exchange believes this proposal will allow the Exchange and MIAX to continue to be able to meet the access demands of new 10Gb ULL network connectivity subscribers and satisfy the ongoing 10Gb ULL connectivity access demands of existing subscribers.

The Exchange believes its proposal to bifurcate the 10Gb ULL networks of the Exchange and MIAX is not designed to permit unfair discrimination between customers, issuers, brokers and dealers because the Exchange believes that bifurcating 10Gb ULL connectivity between the Exchange and MIAX is the most practical way to increase connectivity availability on existing switches, providing fair and consistent access to all Members and potential Members that require 10Gb ULL connectivity access. The proposed change would increase available 10Gb ULL connectivity to all market participants, including Market Makers, EEMs, and Service Bureaus, enabling the Exchange to continue to meet market participants' current and anticipated connectivity needs. The Exchange also notes that certain market participants may choose to not purchase a 10Gb ULL connection to both the Exchange and MIAX if they determine that purchasing connections to both exchanges is not in their business interests or financially beneficial. Similarly, Service Bureaus may also choose to not purchase a 10Gb ULL connection to both the Exchange and MIAX if they determine that there is not sufficient demand from their customers to connect to one or both exchanges. Other Members, particularly EEMs, may choose to purchase 1Gb connectivity instead and use that single connection to access both the Exchange and MIAX.

As described in the above example, if new or existing Members deem it necessary for them to utilize additional ports on each switch, those Members will quickly consume the remaining available ports, leaving very little or no additional ports open for other Members or new Members to gain access. Further, if an existing Member seeks to temporarily increase their 10Gb ULL ports connections while they transition to a new network and/or server infrastructure, they could consume the remaining available ports. In the Exchange's experience, these types of scenarios have become more frequent, leading to the Exchange's proposal to bifurcate the 10Gb ULL networks of the Exchange and MIAX to be able to continue to provide fair access to all market participants of both exchanges. The Exchange, therefore, believes its proposal promotes just and equitable principles of trade, removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general protects investors and the public interest because it will allow MIAX Pearl and MIAX to continue to satisfy ongoing and anticipated future requests for additional 10Gb ULL connectivity access to each market.

Lastly, the Exchange believes that its proposal is consistent with the Exchange's capacity obligations pursuant Regulation SCI.[26] Regulation SCI Rule 1001(a) requires that the Exchange and MIAX establish, maintain, and enforce written policies and procedures reasonably designed to ensure (among other things) that their Regulation SCI systems have levels of capacity adequate to maintain the Exchange's and MIAX's operational capabilities and promote the maintenance of fair and orderly markets.[27] The Exchange's proposal to separate the 10Gb ULL networks of the Exchange and MIAX would mean that any future potential System issue would be limited to only one exchange, narrowing the impact and preventing unnecessary Systems disruptions on the other exchange. This protects investors and the public interest by potentially reducing market disruptions to either MIAX Pearl or MIAX, depending on the issue, as opposed to disrupting both markets from a single event on the shared network. The Exchange believes this proposal supports the Regulation SCI obligations for the Exchange and MIAX in by limiting any potential future risk of a systems issue to one exchange and not impacting the operations or market participants of the other exchange. Bifurcating the networks also allows each exchange to evolve separately, potentially by using different technology to cater to the unique demands of each exchange and their market participants to meet future needs.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition because the bifurcation of the Exchange and MIAX 10Gb ULL networks would affect all Members equally and ensure that the Exchange continues to be able to satisfy all connectivity requests from all Members as requested. The Exchange believes the proposed rule changes will not impose any burden on inter-market competition. In fact, the Exchange believes that not bifurcating the Exchange and MIAX networks could have an adverse impact on inter-market competition because not doing so could hamper the Exchange's ability to expand its network to meet ongoing and future connectivity demand, which could, in turn, limit its ability to compete for Memberships and order flow. Separating its 10Gb ULL network from MIAX would enable the Exchange to better compete with other exchanges by ensuring it can provide adequate connectivity to existing and new Members, which may increase in ability

[25] 15 U.S.C. 78f(b)(5).

[26] 17 CFR 242.1000–1007.

[27] 17 CFR 242.1001(a).

to compete for order flow and deepen its liquidity pool, improving the overall quality of its market. Lastly, the Exchange believes its proposal will not impose any burden on inter-market competition because it would allow the Exchange to operate on a dedicated network in the same manner as other affiliated exchanges who operate on dedicated networks separate from their affiliates.[28]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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 after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [29] and Rule 19b–4(f)(6) [30] 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 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–PEARL–2022–60 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–PEARL–2022–60. 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–PEARL–2022–60 and should be submitted on or before January 17, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–28087 Filed 12–23–22; 8:45 am]

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[28] *See supra* notes 5 and 6.

[29] 15 U.S.C. 78s(b)(3)(A).

[30] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96548; File No. SR–EMERALD–2022–35]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 519C, Mass Cancellation of Trading Interest

December 20, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on December 8, 2022, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the 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 Exchange Rule 519C, Mass Cancellation of Trading Interest.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald,* at MIAX Emerald's principal office, 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 Interpretations and Policies .01 of Exchange Rule 519C, Mass Cancellation

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

of Trading Interest, to provide Members [3] the option of having the Exchange cancel all orders, including GTC Orders,[4] if the Exchange detects a loss of communication on a FIX Order Interface (''FOI'') Session.

Background

Electronic Exchange Members (''EEMs'') [5] connect to the Exchange via the Financial Information eXchange (''FIX'') Protocol.[6] An EEM connects to their assigned FIX port using the MIAX FIX Order Interface (''FOI'') which is a flexible interface that uses the FIX protocol for both application and session level messages. The Exchange relies on heartbeat [7] messages to determine the status of the connection to ensure bi-directional communication remains intact. Upon missing a single heartbeat, FOI will send a *Test Request* message [8] to the Member to check the status of the connection. Upon missing a certain number of heartbeats,[9] FOI will send a logout message and terminate the connection. The Exchange currently offers Members certain order handling risk protection options in this scenario.

Specifically, when a Loss of Communication is detected on a FOI connection the System [10] will logoff the Member's session and (i) cancel all eligible orders for the FIX Session if instructed by the Member upon login, or (ii) cancel all eligible orders identified by the Member. Following a disconnection, a reconnection will not be permitted for a certain period of time (''yy'' seconds). The Exchange shall determine the appropriate period of (''yy'' seconds) and shall notify Members of the value of ''yy'' seconds via Regulatory Circular. In no event shall ''yy'' be less than one (1) second or greater than ten (10) seconds.[11]

At the time the Exchange adopted this functionality the Exchange created an exception for Good 'Til Cancel Orders in Interpretations and Policies .01, which stated, Good 'Til Cancelled (''GTC'') orders, as defined in Rule 516 and PRIME Orders, as defined in Rule 515A, are not eligible for automatic cancellation under paragraph (c) of Rule 519C.[12]

Proposal

The Exchange now proposes to amend Interpretations and Policies .01 to allow GTC orders to also be eligible for cancellation when the Exchange detects a Loss of Communication.

As proposed, if the Exchange determines that there is a Loss of Communication, the Exchange will cancel the orders as described above, additionally, if elected, the Exchange proposes to cancel all GTC orders submitted through that FIX Session. As proposed, Members would need to contact the Exchange's Help Desk,[13] in a form and manner to be determined by the Exchange and communicated via Regulatory Circular, to have this optional order protection (cancellation of GTC orders) configured.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [14] in general, and furthers the objectives of section 6(b)(5) of the Act [15] in particular, in that 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.

The disconnect feature of FIX connections is mandatory, however Members have the option to enable the cancellation of all orders for an entire session or select orders for cancellation on an order-by-order basis, which would result in the cancellation of orders submitted over a FIX Session when such session disconnects. The Exchange believes it is appropriate to offer an additional option for Members to have the Exchange cancel GTC orders from the order book when there is a communication issue between the Member and the Exchange, as a communication issue may or may not be quickly resolved.

Offering to cancel all orders (including GTC orders) allows the Member to customize Exchange risk protection functionality to align to a Member's business needs. Offering this type of order cancellation functionality to Members is consistent with the Act because it enables Members to have greater control over the execution of their orders in the event there is a communication issue with the Exchange. The proposed order cancellation functionality is designed to mitigate the risk of a missed execution associated with a loss of communication with the Exchange. The proposed rule change is not unfairly discriminatory among market participants, as it is available equally to all market participants utilizing a FOI connection to the Exchange.

The Exchange believes that the proposed rule change will assist with the maintenance of a fair and orderly market by providing Members with greater control over their resting orders. The Exchange's proposal is consistent with the Act because it will mitigate the risk of potential erroneous or unintended executions associated with a loss of communication which protects investors and the public interest. Additionally, the proposed rule adds another level of risk protection for Members and protects investors and the public interest by increasing the risk protection options available to Members of the Exchange.

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] A Good 'til Cancelled or ''GTC'' Order is an order to buy or sell which remains in effect until it is either executed, cancelled or the underlying option expires. *See* Exchange Rule 516(l).

[5] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[6] The Financial Information eXchange (FIX) is a vendor-neutral electronic communications protocol for the international real-time exchange of securities transaction information. Scott, Gordon, Financial Information eXchange (FIX), Investopedia (June 20, 2022), *https://www.investopedia.com/terms/f/financial-information-exchange.asp*.

[7] A ''Heartbeat'' message is a communication which acts as a virtual pulse between the Exchange System and the Member's system. The heartbeat message sent by the Member and received by the Exchange allows the Exchange to continually monitor its connection with the Member. *See* Interpretations and Policies .02(i) of Exchange Rule 519C.

[8] The test request message is a FIX Protocol message that forces a heartbeat from the opposing application. The test request message checks sequence numbers or verifies communication line status. The opposite application responds to the Test Request with a Heartbeat containing the Test Request ID. Financial Information Exchange Protocol (FIX), Version 4.2 with errata. May 1, 2001.

[9] The Exchange notes that the current System setting is two (2) heartbeats, and that any change to this setting will be determined by the Exchange and communicated to Members via Regulatory Circular.

[10] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[11] *See* Exchange Rule 519C(c)(2).

[12] *See* Interpretations and Policies .01 of Exchange Rule 519C.

[13] The term ''Help Desk'' means the Exchange's control room consisting of Exchange staff authorized to make certain trading determinations on behalf of the Exchange. The Help Desk shall report to and be supervised by a senior executive officer of the Exchange. *See* Exchange Rule 100.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe that the proposed rule change to provide an additional risk protection imposes any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that adding an optional risk protection benefits all Members on the Exchange that use a FOI connection as any Member with a FOI connection can elect to use the risk protection described in the proposed rule.

The Exchange does not believe the proposed rule change will impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. For all the reasons stated, 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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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 after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) [17] 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 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–EMERALD–2022–35.

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–EMERALD–2022–35. 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–EMERALD–2022–35, and should be submitted on or before January 17, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

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[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96542; File No. SR–NASDAQ–2022–076]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Equity 4, Rule 4754 Regarding Close Eligible Interest

December 20, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 12, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 Equity 4, Rule 4754. The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Equity 4, Rule 4754 [3] as it relates to Close Eligible Interest.[4] Specifically, the Exchange proposes to amend (a)(1) of Rule 4754 to specify that: (1) the System will delay processing any full cancellation request [5] for Close Eligible Interest made during the Nasdaq Closing Cross until such time as the Nasdaq Closing Cross concludes, except for securities in a halt or pause; and (2) during a halt or pause, the System will process any cancellation request for Close Eligible Interest made for such halted or paused security during the Nasdaq Closing Cross.

The Nasdaq Closing Cross is a transparent auction process that determines a single price for the close. Members can submit Limit on Close (''LOC'') Orders,[6] Market on Close (''MOC'') Orders,[7] and Imbalance Only (''IO'') Orders [8] that are available to participate in the Nasdaq Closing Cross along with Close Eligible Interest. LOC Orders, MOC Orders, and IO Orders cannot be cancelled or modified at or after 3:58 p.m. ET (or at or after two minutes prior to the early closing time on a day when Nasdaq closes early).[9] In contrast, currently, Close Eligible Interest on the continuous book is eligible for cancellation during the Nasdaq Closing Cross.

At 4:00 p.m. ET (or at the early closing time on a day when Nasdaq closes early), the Exchange executes the Nasdaq Closing Cross at a price determined in accordance with Rule 4754(b)(2). The cross in each security is performed sequentially in a random order each day and in total takes approximately 700 milliseconds on average. Therefore, the time between the commencement and conclusion of the Nasdaq Closing Cross for a particular security can range from less than one millisecond up to 700 milliseconds or greater. During this gap, currently, cancellations of Close Eligible Interest on the continuous book can continue to take place, which can affect the closing price of a security.

In addition to impacting the closing price of the security, allowing cancellations of Close Eligible Interest during the Nasdaq Closing Cross has another negative impact in that it causes divergence between the closing price and the Order Imbalance Indicator. The Order Imbalance Indicator disseminates information about MOC Orders, LOC Orders, IO Orders, and Close Eligible Interest and the price at which those orders would execute at the time of dissemination. The Exchange disseminates an Order Imbalance Indicator every second until market close beginning at 3:55 p.m. ET (or five minutes prior to the early closing time on a day when Nasdaq closes early). The Order Imbalance Indicator is intended to facilitate participation in the close. Therefore, full cancellations of Close Eligible Interest during the Nasdaq Closing Cross that cause divergences between the Order Imbalance Indicator and the closing price are undesirable.[10]

The proposed rule change to delay processing of any full cancellation request for Close Eligible Interest made during the Nasdaq Closing Cross until the Nasdaq Closing Cross concludes (except for securities in a halt or pause) would better align with the practice to not allow cancellations of other orders available to participate in the Nasdaq Closing Cross (*i.e.,* LOC Orders, MOC Orders, and IO Orders) during the Nasdaq Closing Cross. In addition, this change would provide for a more stable closing price that is more in line with the Order Imbalance Indicator and participants' expectations. The proposed rule change would also clarify that, during a halt or pause, the System would process any cancellation request for Close Eligible Interest made for such halted or paused security during the Nasdaq Closing Cross, consistent with current practice.

Implementation Date

The Exchange will issue an Equities Trader Alert to provide notification of the change and relevant date of implementation prior to introducing the new functionality.[11]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Section 6(b)(5) of the Act,[13] 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.

The Exchange believes that its proposal will promote just and equitable principles of trade because it will create a more standardized process that does not allow for full cancellation of Close Eligible Interest during the Nasdaq Closing Cross. As explained above, the Exchange currently allows for cancellation of Close Eligible Interest during the Nasdaq Closing Cross yet does not allow for full or partial cancellation of other orders during the Nasdaq Closing Cross. The Exchange believes that the proposed change to no longer allow for full cancellation of Close Eligible Interest during the Nasdaq Closing Cross (unless the securities are in a halt or pause) will benefit investors by providing a more consistent experience for members and investors, and reducing any potential confusion regarding Nasdaq's closing processes.

Furthermore, the current process of allowing for cancellations of Close Eligible Interest during the Nasdaq Closing Cross can impact the closing price of the security and cause divergence from the Order Imbalance Indicator. The Exchange believes that delaying full cancellations until the end of the Nasdaq Closing Cross (unless the securities are in a halt or pause) would facilitate fair and orderly pricing at the Nasdaq Closing Cross, consistent with participants' expectations, thereby removing impediments to and

[3] Hereinafter, references to the Rule 4000 Series shall mean the Rule Series set forth in Equity 4 of the Exchange's Rulebook.

[4] ''Close Eligible Interest'' means any quotation or any order that may be entered into the system and designated with a time-in-force of SDAY, SGTC, MDAY, MGTC, SHEX, or GTMC. *See* Rule 4754(a)(1).

[5] Partial cancellation requests for Close Eligible Interest would continue to be processed during the Nasdaq Closing Cross.

[6] A ''Limit On Close Order'' or ''LOC Order'' is an Order Type entered with a price that may be executed only in the Nasdaq Closing Cross or the LULD Closing Cross, and only if the price determined by the Nasdaq Closing Cross or the LULD Closing Cross is equal to or better than the price at which the LOC Order was entered. *See* Rule 4702(b)(12).

[7] A ''Market On Close Order'' or ''MOC Order'' is an Order Type entered without a price that may be executed only during the Nasdaq Closing Cross. *See* Rule 4702(b)(11).

[8] An ''Imbalance Only Order'' or ''IO Order'' is an Order entered with a price that may be executed only in the Nasdaq Closing Cross and only against MOC Orders or LOC Orders. *See* Rule 4702(b)(13).

[9] *See* Rule 4702(b)(11)–(13).

[10] Although partial cancellations of Close Eligible Interest during the Nasdaq Closing Cross could also impact the closing price of the security and cause a divergence between the closing price and the Order Imbalance Indicator, in practice, partial cancellations of Close Eligible Interest during the Nasdaq Closing Cross occur less frequently and have less impact on the closing price than full cancellations.

[11] The proposed functionality herein was recently produced and taken out of production, pending filing with the Commission.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

perfecting the mechanism of a free and open market and a national market system. The Exchange's proposal to clarify that, during a halt or pause, the System will process any cancellation request for Close Eligible Interest made for such halted or paused security during the Nasdaq Closing Cross, will provide increased clarity and help limit any potential confusion in the future, 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 not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to create a more standardized process and improve the Nasdaq Closing Cross process by delaying the processing of any full cancellation request for Close Eligible Interest made for any securities not halted or paused during the Nasdaq Closing Cross until such time as the Nasdaq Closing Cross concludes. The change would apply to all full cancellation requests in Close Eligible Interest (except for securities in a halt or pause) and would benefit participants by providing for a more stable closing price that is more in line with the Order Imbalance Indicator, consistent with expectations. The proposed rule change would also clarify that, during a halt or pause, the System will process any cancellation request for Close Eligible Interest made for such halted or paused security during the Nasdaq Closing Cross, benefiting participants by providing increased clarity and helping to limit any potential confusion in the future.

The Exchange does not believe that the proposed change to (a) delay the processing of any full cancellation request for Close Eligible Interest made during the Nasdaq Closing Cross until the Nasdaq Closing Cross ends (except for securities in a halt or pause) and (b) clarify that, during a halt or pause, the System will process any cancellation request for Close Eligible Interest made for such halted or paused security during the Nasdaq Closing Cross, will have any significant impact on competition. The Exchange operates in a highly competitive market in which market participants can easily direct their Orders to competing venues, including off-exchange venues. In such an environment, the Exchange must continually review and consider adjusting the services it offers and the requirements it imposes to remain competitive with other venues. Therefore, the Exchange believes that the proposed change in interpretation reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were 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[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. Rule 19b–4(f)(6)(iii), however, permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the operative delay so that the proposal may become operative immediately upon filing. The proposed rule will permit Nasdaq to delay processing full cancellation requests for Close Eligible Interest during the Nasdaq Closing Cross until conclusion of the Nasdaq Closing Cross (except for securities in a halt or pause). Nasdaq represents that the proposal will help prevent divergence from the Order Imbalance Indicator and facilitate fair and orderly pricing at the Nasdaq Closing Cross, consistent with participants' expectations. The Commission thus believes that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposal 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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2022–076 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2022–076. 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

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[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).

comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–076, and should be submitted on or before January 17, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–28079 Filed 12–23–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96543; File No. SR–DTC–2022–013]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Reorganizations Guide and the Fee Guide

December 20, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 15, 2022, 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 purpose of the proposed rule change is to amend the Reorganizations Guide to (i) provide Participants with the option to submit instructions for the withdrawal of an earlier acceptance of an Automated Tender Offer Program (''ATOP'')-eligible[5] offer (each, an ''ATOP Offer'') via Application Program Interface (''API'') and ISO 20022 real-time messaging (collectively, ''Automated Instruction Messaging''), (ii) postpone the retirement of DTC's legacy computer-to-computer facility (''CCF'') files for corporate actions entitlements and allocations (''CCF Entitlements and Allocations Files'')[6] to July 1, 2024, and (iii) make technical and ministerial changes. In addition, DTC is proposing to amend the Fee Guide to continue to charge Participants that consume CCF Entitlements and Allocations Files after December 31, 2022 the CCF File Fee of $50,000, as described in greater detail below.[7]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Reorganizations Guide to (i) provide Participants with the option to submit instructions for the withdrawal of an earlier acceptance of an Automated Tender Offer Program (''ATOP'')-eligible[8] offer (each, an ''ATOP Offer'') via Application Program Interface (''API'') and ISO 20022 real-time messaging (collectively, ''Automated Instruction Messaging''), (ii) postpone the retirement of DTC's legacy computer-to-computer facility (''CCF'') files for corporate actions entitlements and allocations (''CCF Entitlements and Allocations Files'')[9] to July 1, 2024, and (iii) make technical and ministerial changes. In addition, DTC is proposing to amend the Fee Guide to continue to charge Participants that consume CCF Entitlements and Allocations Files after December 31, 2022 the CCF File Fee of $50,000, as discussed more fully below.

(i) Automated Instruction Messaging

A. Background

On July 7, 2021, DTC filed a rule filing[10] (the ''ATOP Automated Messaging Filing'') that provided Participants with the option to use Automated Instruction Messaging to submit acceptance, protect, and cover of protect instructions (each, an ''Acceptance Instruction'') for ATOP Offers instead of submitting those instructions through the Participant Tender Offer Program (''PTOP'') or Voluntary Tenders and Exchanges functions through PTS and PBS, respectively.[11]

As described in the ATOP Automated Messaging Filing, the submission of voluntary reorganizations instructions through PTS and PBS is a nonautomated key-entry process, and there are certain potential risks and costs associated with manual processing, particularly in connection with voluntary reorganizations instructions. Nonautomated input may increase the likelihood of errors, which can result in rejected instructions or erroneous

[17] 17 CFR 200.30–3(a)(12), (59).

[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] ATOP is a DTC program through which Participant instructions are transmitted to the agent for an ATOP offer and through which a participant can tender its securities to the agent's account at DTC.

[6] There are three types of CCF files representing the corporate actions lifecycle: corporate actions announcements (''CCF Announcements Files''); the CCF Entitlements and Allocations Files; and corporate actions instructions from Participants through CCF files (''CCF Corporate Actions Instructions Files''). All CCF Announcement Files were retired as of December 31, 2018. *See* Securities Exchange Act Release No. 79746 (January 5, 2017), 82 FR 3372 (January 11, 2017) (SR–DTC–2016–014).

[7] Each term not otherwise defined herein has its respective meaning as set forth in the Rules, By-Laws and Organization Certificate of DTC (the ''Rules''), the Guide to the DTC Fee Schedule (''Fee Guide''), and the Reorganizations Service Guide (the ''Reorganizations Guide''), *available at http://www.dtcc.com/legal/rules-and-procedures.aspx.*

[8] ATOP is a DTC program through which Participant instructions are transmitted to the agent for an ATOP offer and through which a participant can tender its securities to the agent's account at DTC.

[9] There are three types of CCF files representing the corporate actions lifecycle: corporate actions announcements (''CCF Announcements Files''); the CCF Entitlements and Allocations Files; and corporate actions instructions from Participants through CCF files (''CCF Corporate Actions Instructions Files''). All CCF Announcement Files were retired as of December 31, 2018. *See* Securities Exchange Act Release No. 79746 (January 5, 2017), 82 FR 3372 (January 11, 2017) (SR–DTC–2016–014).

[10] *See* Securities Exchange Act Release No. 92339 (July 7, 2021), 86 FR 36810 (July 13, 2021) (SR–DTC–2021–010). In addition, DTC subsequently filed a rule filing that similarly provided Participants with the option to use Automated Instruction Messaging to submit acceptance, protect, and cover of protect instructions for Automated Subscription Offer Program and APUT offers. *See* Securities Exchange Act Release No. 95197 (July 5, 2022), 87 FR 41153 (July 11, 2022) (SR–DTC–2022–007).

[11] PTS (Participant Terminal System) and PBS (Participant Browser System) are user interfaces for DTC settlement and asset services functions. PTS is mainframe-based, and PBS is web-based with a mainframe back-end. Participants may use either PTS or PBS, as they are functionally equivalent. PTOP and Voluntary Tenders and Exchanges are functions of PTS and PBS, respectively, that are currently used by Participants to submit instructions, submit protects, submit cover of protects, submit cover of protects on behalf of another Participant, and submit withdrawals on various voluntary reorganization events.

elections. Rejected instructions and erroneous elections can delay the submission of the instructions for voluntary offers, which typically have to be submitted within a short timeframe. Further, because information about a voluntary offer and the compilation and transmission of instructions flows across different market segments, the lack of automation and standardization can also lead to errors along the chain.

ISO 20022 is a standard that provides the financial industry with a common language to capture business transactions and associated message flows. The benefits offered by ISO 20022 include, but are not limited to (i) greater straight through processing by utilizing a data model that conforms to market practice and (ii) improved accuracy and less processing risk due to enhanced data elements. APIs provides enhanced flexibility for Participants, making the process of accessing from, and transmitting information to, DTC and its downstream customers more efficient. The flexibility of APIs and its use of modern programming languages provide benefits that include but are not limited to (i) less frequent maintenance, (ii) client development and implementation can be quicker to market, and (iii) more efficient integration channels.

B. Automated Instruction Messaging

DTC is proposing to enhance Automated Instruction Messaging for ATOP Offers by providing Participants with the ability to use Automated Instruction Messaging to submit an instruction to withdraw an Acceptance Instruction.[12] Automated Instruction Messaging for withdrawal instructions must be for the full quantity of the original Acceptance Instruction. Participants that are submitting withdrawal instructions for less than the full quantity must continue to submit those instructions via PTS/PBS.

As with Automated Instruction Messaging for other actions for ATOP, ASOP and APUT eligible offers, Automated Instruction Messaging for withdrawal instructions for an ATOP Offer would consist of (i) Automated Instruction Messages for the input of instructions and (ii) Automated Response Messages for feedback and status output with respect to submitted instructions. The ISO 20022 Corporate Action Instruction (CAIN) message and the API POST function are Automated Instruction Messages. The ISO 20022 Corporate Action Instruction Status Advice (CAIS) message and the API GET function are Automated Response Messages.

As noted above, automating the submission of withdrawal instructions for ATOP Offers would streamline the flow of information and reduce the costs, errors and risks that are associated with nonautomated processing. Accordingly, pursuant to the proposed rule change, DTC would enhance the ability of Participants to automate and standardize the submission of withdrawal instructions for ATOP Offers through Automated Instruction Messaging.

C. Proposed Rule Changes

Pursuant to the proposed rule change, DTC is proposing to:

1. Add references to ''Automated Instruction Messaging'' or ''Automated Instruction Message,'' as context requires, where other types of instruction input for withdrawals of instructions for ATOP Offers (*e.g.,* PTS PTOP and PBS Voluntary Tenders and Exchanges) are referenced.

2. In the ''Automated Instruction Messaging'' Section:

a. Amend the text of footnote 1 to read, ''Automated Instruction Messaging for withdrawal instructions for ATOP-eligible offers will be available in Q1 of 2023.''

b. At the bottom of the enumerated list of actions for ATOP Offers that can be taken via Automated Instruction Messaging, insert ''5. Withdrawal (for full amount of original instruction only).''

c. Amend the note under the enumerated list of actions for ATOP Offers that can be taken via Automated Instruction Messaging to state: ''Withdrawal instructions submitted via Automated Instruction Messaging must be for the full quantity of the original instruction. Partial withdrawal instructions for ATOP-eligible offers must be performed via PTS/PBS and cannot be instructed via Automated Instruction Message.''

3. In the ''Instructions/Expirations'' section, amend the note ''All withdrawal/cancellation instructions must be performed via PTS/PBS,'' to read, ''Partial withdrawal instructions must be performed via PTS/PBS.''

4. At the end of the first paragraph of the ''Withdrawing an Acceptance of an ATOP-Eligible Offer'' section, insert the following sentence: ''Note: Only full withdrawals will be accepted via Automated Instruction Messaging. Partial withdrawal instructions must be performed via PTS/PBS.''

5. Amend the second paragraph in the ''Checklist for Withdrawing an Acceptance'' section to read, ''Enter and transmit an instruction to withdraw the acceptance via PTS PTOP, PBS Voluntary Tenders and Exchanges, or Automated Instruction Messaging. For instructions transmitted via PTS/PBS, the withdrawal request can be for all or any part of the acceptance previously submitted, and you can submit more than one withdrawal request as long as the quantity of securities indicated in the withdrawal instructions does not exceed the original quantity of the acceptance. Withdrawal instructions submitted via Automated Instruction Messaging must be for the full quantity of the original instruction.''

6. Amend the first bullet under the fourth paragraph in the ''Checklist for Withdrawing an Acceptance'' section to read, ''You can inquire about your withdrawal instructions and the status thereof via the PTS PTOP or PBS Voluntary Tenders and Exchanges function's inquiry feature, or via Automated Instruction Messaging.''

7. Make ministerial changes for clarity, to correct typos and omissions and to enhance conformity and readability, including, but not limited to:

a. In the ''Important Legal Information'' replace ''Copyright © 2022'' with ''Copyright © 2023.''

b. Delete all instances of the following sentences: ''If possible, DTC will attempt to notify you of the rejection, but DTC cannot guarantee such notification,'' ''If practicable, DTC will attempt to notify you of the rejection, but cannot guarantee such notification,'' ''DTC will attempt to notify your designated coordinator by telephone of the rejection, but DTC cannot guarantee that this will be done,'' and ''If rejection is for a reason other than that your tender price was not accepted or that a pro rata portion of your tender was not accepted, DTC will attempt to notify you by telephone, calling first the coordinator (s) at the telephone number (s) entered on the instructions form, but takes no responsibility therefor.'' DTC is proposing to delete these sentences in order to make it clear that Participants are solely responsible for monitoring their accounts and the response messages to ensure that they properly submitted their instructions and that the instructions were accepted.

c. In ''How to View Mandatory and Voluntary Reorganization Announcements'' section, delete the footnote that reads ''The RIPS function for mandatory reorganizations announcements will be retired on November 16, 2020.'' DTC is proposing to delete this sentence because RIPS for

[12] DTC notes that withdrawal actions—whether through Automated Instruction Messaging or PTS/PBS—are only available when provided for under the terms of the applicable ATOP Offer.

mandatory reorganizations has been retired.

(ii) CCF Entitlements and Allocations Files and CCF File Fee

A. Background

On November 19, 2020, DTC filed a rule change (the ''2021 CCF Retirement Filing'') [13] that amended the Reorganizations Guide and the Fee Guide to (i) set a retirement date for CCF Entitlements and Allocations Files of January 1, 2022, and (ii) apply a $50,000 CCF File Fee, per File Category (Pre-Allocation or Allocation/Post-Allocation) of CCF Entitlements and Allocations Files,[14] to Participants that continued to consume CCF Entitlements and Allocations Files between January 1, 2021 and December 31, 2021. The CCF File Fee was charged to the Account of the Participant upon the Participant's first receipt of CCF Entitlements and Allocations Files in a particular File Category during 2021. The CCF File Fee covered all CCF Entitlements and Allocations Files within that File Category during 2021.

Many Participants completed their adoption of ISO 20022 messaging for entitlements and allocations information, and their migration from the CCF Entitlements and Allocations Files, before the January 1, 2022 retirement date. However, some Participants had not completed their system development for the ISO 20022 messaging requested that DTC continue to offer the CCF Entitlements and Allocations Files for another year. Accordingly, on December 29, 2021, DTC filed a rule change (''2022 CCF Retirement Filing'') [15] to postpone the retirement date of the CCF Entitlements and Allocation Files to January 1, 2023, and to charge Participants the $50,000 CCF File Fee for each File Category of CCF Entitlements and Allocations Files that they consumed between January 1, 2022 and December 31, 2022. The CCF File Fee was charged to the Account of the Participant upon the Participant's first receipt of CCF Entitlements and Allocations Files in a particular File Category during 2022. The CCF File Fee covered all CCF Entitlements and Allocations Files within that File Category during 2022.

As discussed in the 2021 and 2022 CCF Retirement Filings, DTC has been informing Participants that corporate actions CCF files [16] will be retired and will be replaced by ISO 20022 messaging since 2011.[17] As noted above, ISO 20022 messaging offers enhanced efficiency and transparency in the corporate action lifecycle because, in contrast to the proprietary function and activity codes of CCF Files, ISO 20022 is a business-model-based standard for the development of messages for the international financial services industry.

DTC has been working with Participants to specifically support their orderly transition from CCF Entitlements and Allocations Files to ISO 20022 messaging since 2013. DTC began providing Participants with parallel entitlements and allocations ISO 20022 messaging in 2013 (Distributions), 2015 (Redemptions) and 2017 (Reorganizations). In addition, since 2016,DTC had been communicating with Participants about the deadline for retirement of the CCF Entitlements and Allocation Files and postponed the projected retirement date multiple times.[18] Until the 2021 CCF Retirement Filing, DTC had not imposed a fee on Participants' continued use of CCF Entitlements and Allocations Files.

B. Proposed Rule Change

Almost all Participants have now successfully migrated from CCF Entitlements and Allocations Files to ISO 20022 messaging. There are, however, a few Participants that have indicated to DTC that, for reasons internal to their respective firms, they would not be able to complete their migration by the end of 2022.

Therefore, pursuant to this proposed rule change, DTC would postpone the retirement date of the CCF Entitlements and Allocation Files to July 1, 2024, and would continue to charge each Participant the CCF File Fee of $50,000 for each File Category of CCF Entitlements and Allocations Files that it consumes during each of the following fee periods (each, a ''Fee Period''): (i) from January 1, 2023 through December 31, 2023, and (ii) from January 1, 2024 through June 30, 2024. The CCF File Fee would be charged to the Account of the Participant, upon the Participant's first receipt of CCF Entitlements and Allocations Files in a particular File Category during that specific Fee Period. The CCF File Fee would cover all CCF Entitlements and Allocations Files within that File Category during that Fee Period.

Pursuant to the proposed rule change, DTC would amend the description of the CCF File Fee in the Fee Guide to conform with the proposed rule change. DTC would also amend the Reorganizations Guide to reflect the July 1, 2024, retirement date for CCF Entitlements and Allocations Files. Specifically, in the ''Preparing to Use the Services'' subsection of the ''How Reorganizations Work'' section of the Reorganizations Guide, DTC is proposing to replace ''*CCF files associated with entitlements and allocations will be retired as of January 1, 2023'' with ''*CCF files associated with entitlements and allocations will be retired as of July 1, 2024.''

Implementation Date

DTC will implement the proposed changes on January 1, 2023. DTC will announce the implementation date of the proposed rule change in an Important Notice posted on its website.

As proposed, a legend would be added to the Reorganizations Guide and the Fee Guide stating there are changes that became effective upon filing with the Commission but have not yet been implemented. The proposed legend also would include that the implementation date will be January 1, 2023. In addition, the proposed legend would state that the legend would automatically be removed upon the implementation of the proposed changes.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and

[13] *See* Securities Exchange Act Release No. 90490 (November 23, 2020), 85 FR 76645 (November 30, 2020) (SR–DTC–2020–016).

[14] Each of the CCF Entitlements and Allocations Files falls into one of two categories (each, a ''File Category''): (i) pre-allocation (''Pre-Allocation CCF Files''), which includes files containing a Participant's allocation projections and entitlements, or (ii) allocation/post-allocation (''Allocation/Post-Allocation CCF Files''), which includes files containing information on a Participant's allocations and pending allocations. *See* Important Notice 13851–20 (August 27, 2020), *available at https://www.dtcc.com/legal/important-notices.*

[15] *See* Securities Exchange Act Release No. 93885 (December 30, 2021), 87 FR 528 (January 5, 2022) (SR–DTC–2021–018).

[16] There are three event groups for CCF files for corporate actions. Participants subscribe to the CCF files for each event group separately. The event groups are (i) distributions (''Distributions''), such as cash and stock dividends, principal and interest, and capital gain distributions; (ii) redemptions (''Redemptions''), such as full and partial calls, final paydowns, and maturities; and (iii) reorganizations (''Reorganizations''), which include both mandatory and voluntary reorganizations such as exchange offers, conversions, Dutch auctions, mergers, puts, reverse stock splits, tender offers, and warrant exercises.

[17] *See* Securities Exchange Act Release No. 63886 (February 10, 2011), 76 FR 9070 (February 16, 2011) (SR–DTC–2011–02) (indicating that DTC would continue to support its legacy proprietary CCF files until 2015).

[18] *See* Important Notice 2538–16 (January 21, 2016), *supra* note 15; Important Notice 4381–16 (November 4, 2016), *supra* note 15; Important Notice 5099–17 (February 2017), *supra* note 15; Important Notice 7488–18 (February 28, 2018), *supra* note 15; Important Notice 9861–18 (October 9, 2018), *supra* note 15.

accurate clearance and settlement of securities transactions.[19]

The proposed rule change would amend the Reorganizations Guide to provide Participants with the option to use Automated Instruction Messaging for withdrawal instructions for ATOP Offers. As discussed above, Automated Instruction Messaging provides greater straight-through processing, improved accuracy, more efficient integration channels and less processing risk than nonautomated processing.

DTC believes that the proposed rule change to amend the Reorganizations Guide to make technical and clarifying changes would enhance the clarity and transparency of the Reorganizations Guide. By enhancing the clarity and transparency of the Reorganizations Guide, the proposed rule change would allow Participants to more efficiently and effectively conduct their business in connection with processing reorganization events and associated securities transactions. Based on the foregoing, DTC believes that the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions, consistent with section 17A(b)(3)(F) of the Act, cited above.

In addition, the proposed rule change would (i) postpone the retirement of CCF Entitlements and Allocations Files to July 1, 2024, and (ii) continue the application of a CCF File Fee of $50,000 to Participants that continue to consume CCF Entitlements and Allocations Files after December 31, 2022. By postponing the retirement of CCF Entitlements and Allocations Files to July 1, 2024, the proposed rule change would allow Participants to minimize potential business interruptions by undertaking an orderly and organized migration from CCF files to the more efficient ISO 20022 standard. Similarly, by continuing to charge a CCF File Fee of $50,000 to those Participants that continue to receive CCF Entitlements and Allocations Files after December 31, 2022, the proposed rule change would encourage the few remaining Participants still utilizing CCF Entitlements and Allocations Files to accelerate system development and their adoption of the ISO 20022 standard. In this manner, the proposed rule change would encourage and facilitate the transition to the ISO 20022 standard, which provides efficiencies and enhanced transparency in processing corporate actions and the settlement activities related thereto. Accordingly, DTC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of 17A(b)(3)(F) of the Act, cited above.

Section 17A(b)(3)(D) of the Act requires that the Rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Participants.[20] DTC believes that the proposed rule change to continue to apply the $50,000 CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files after December 31, 2022 would provide for the equitable allocation of reasonable fees.

DTC believes that the proposed application of the CCF File Fee would be equitably allocated because the CCF File Fee (i) would only be charged to those Participants that have delayed their migration from CCF Entitlements and Allocations Files beyond December 31, 2022 [21] and (ii) would be applied in accordance with the Participant's use of a particular File Category during a specific Fee Period.

Further, DTC believes that the continued application of the $50,000 CCF File Fee would be reasonable. As discussed above, Participants that did not complete their migration to ISO 20022 by January 1, 2021, or January 1, 2022, were charged the $50,000 CCF File Fee for each File Category of CCF Entitlements and Allocations Files that they consumed during each calendar year. Most Participants have now completed their migration, which DTC believes is due, in part, to the application of the CCF File Fee. Based on this prior experience with the CCF File Fee, DTC believes that the CCF File Fee in the amount of $50,000 provides the necessary encouragement for Participants to accelerate their system development for their adoption of the ISO 20022 standard for entitlements and allocations information.[22] Further, during the prior applications of the CCF File Fee to CCF Entitlements and Allocations Files, DTC had not received any negative feedback from Participants that suggested that the $50,000 fee was overly burdensome.

Therefore, DTC believes that the proposed rule change regarding the CCF File Fee provides for the equitable allocation of reasonable dues, fees, and other charges among its Participants, consistent with 17A(b)(3)(D) of the Act, cited above.

(B) Clearing Agency's Statement on Burden on Competition

DTC believes that the proposed rule change to provide Participants with the option to use Automated Instruction Messaging for withdrawal instructions for ATOP Offers would not have any impact on competition. Because Automated Instruction Messaging is an optional service that would be available to all Participants in connection with ATOP Offers, DTC does not believe that the proposed rule change would impose a burden on competition.[23] In addition, DTC believes that the proposed rule change to make technical and ministerial changes to the Reorganizations Guide, would not have any impact on competition because it would merely enhance the clarity of the procedures relating to ATOP Offers. In light of the foregoing, DTC does not believe that the proposed rule changes would impose a burden on competition.[24]

DTC believes that the proposed rule change with respect to postponing the retirement of CCF Entitlements and Allocations Files to July 1, 2024 would not have any impact on competition. The proposed rule change would provide any Participant that has not completed its migration from CCF Entitlements and Allocation Files with additional time to complete its testing and development of its systems and finalize the transition to ISO 20022 messaging. Therefore, DTC believes that the proposed rule change with respect to postponing the retirement of CCF Entitlements and Allocations Files to July 1, 2024 would not have a burden on competition.[25]

DTC believes that the proposed rule change with respect to amending the Fee Guide to continue to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files after December 31, 2022 could have an impact on competition because it could create a burden on competition.[26] Although the proposed application of the CCF File Fee is designed to incentivize Participants to accelerate and complete their adoption of the ISO 20022 standard, DTC recognizes and appreciates that continuing to charge

[19] 15 U.S.C. 78q–1(b)(3)(F).

[20] 15 U.S.C. 78q–1(b)(3)(D).

[21] As noted above, DTC has been communicating with Participants about the migration from CCF files to the ISO 20022 standard for corporate actions events since 2011. Since 2013, DTC has been communicating with Participants about targeted retirement dates for CCF Entitlements and Allocations Files and has, at the request of Participants, postponed the projected dates numerous times.

[22] The CCF File Fee is not designed to cover costs incurred by DTC as a result of continuing to service CCF files.

[23] 15 U.S.C. 78q–1(b)(3)(I).

[24] *Id.*

[25] 15 U.S.C. 78q–1(b)(3)(I).

[26] *Id.*

the fee could negatively affect such Participants' operating costs. However, DTC believes that any burden on competition would not be significant and would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by 17A(b)(3)(I) of the Act.[27]

DTC believes any burden on competition would not be significant because (i) the fee would only be charged once per File Category, upon the Participant's first receipt of CCF Entitlements and Allocations Files for a File Category during a particular Fee Period, and (ii) the application of the CCF File Fee for a File Category would cover the consumption of all CCF Entitlements and Allocations Files within that File Category during that Fee Period. In addition, based on DTC's prior use of the CCF File Fee for CCF Entitlements and Application Files, DTC has no indication that the amount of the fee creates a significant burden on any Participant.

DTC believes that any burden on competition that may be created by the proposed change to amend the Fee Guide to continue to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files after December 31, 2022 would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by 17A(b)(3)(I) of the Act.[28] DTC believes that this proposed change would be necessary because some Participants have yet to adopt the ISO 20022 standard, despite at least nine years of communication and prompting on the issue.[29] As noted above, the ISO 20022 standard provides efficiencies and enhanced transparency in processing corporate actions and the settlement activities related thereto. Thus, DTC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with 17A(b)(3)(F) of the Act.[30]

DTC believes that the proposed rule change to continue to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files after December 31, 2022 would be appropriate in furtherance of the purposes of the Act, as permitted by 17A(b)(3)(I) of the Act.[31] As discussed above, Participants that did not complete their migration to ISO 20022 by January 1, 2021 or by January 1, 2022 were charged the $50,000 CCF File Fee for each File Category of CCF Entitlements and Allocations Files that they consumed during the each calendar year. Most Participants have now completed their migration, which DTC believes is due, in part, to the application of the $50,000 CCF File Fee. DTC's prior experience with the $50,000 CCF File Fee illustrates that a $50,000 CCF File Fee provides the necessary encouragement for Participants to accelerate their system development for the full adoption of the ISO 20022 standard. Further, during the previous application of the CCF File Fee to CCF Entitlements and Allocations Files, DTC had not received any negative feedback from Participants that suggested that the $50,000 fee was overly burdensome. Accordingly, DTC believes that the continued application of the $50,000 CCF File Fee would be appropriate here in order to incentivize the remaining Participants to accelerate their migration to the ISO 20022 standard. In addition, as discussed above, DTC believes that the proposed continued application of the CCF File Fee would be equitably allocated because the CCF File Fee (i) would only be charged to those Participants that have delayed their migration from CCF Entitlements and Allocations beyond December 31, 2022, and (ii) would be applied in accordance with the Participant's use of a particular File Category during a specific Fee Period.

Therefore, for these reasons, DTC believes that a perceived competitive burden of the proposed rule change to continue to apply the CCF File Fee to Participants that continue to consume CCF Entitlements and Allocations Files after December 31, 2022, would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by 17A(b)(3)(I) of the Act.[32]

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not received or solicited any written comments relating to this proposal. If any written comments are received, they would be publicly filed as an Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at https://www.sec.gov/regulatory-actions/how-to-submit-comments.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to 19(b)(3)(A)[33] of the Act and paragraph (f)[34] of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–DTC–2022–013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–DTC–2022–013. 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

[27] *Id.*

[28] *Id.*

[29] *See supra* notes 17 and 18.

[30] 15 U.S.C. 78q–1(b)(3)(F).

[31] 15 U.S.C. 78q–1(b)(3)(I).

[32] *Id.*

[33] 15 U.S.C. 78s(b)(3)(A).

[34] 17 CFR 240.19b–4(f).

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–2022–013 and should be submitted on or before January 17, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–28080 Filed 12–23–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96545; File No. SR–MIAX–2022–48]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To No Longer Operate MIAX's 10 Gigabit Ultra-Low Latency Connectivity on a Single Shared Network With Its Affiliate, MIAX PEARL, LLC

December 20, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 16, 2022, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a 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 is filing a proposal to no longer operate 10 gigabit (''Gb'') ultra-low latency (''ULL'') connectivity to the Exchange on a single shared network with its affiliate, MIAX PEARL, LLC (''MIAX Pearl''), due to ever-increasing capacity constraints and to accommodate anticipated access needs for Members [3] and other market participants.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, 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 no longer operate 10Gb ULL connectivity to the Exchange on a single shared network with its affiliate, MIAX Pearl, due to ever-increasing capacity constraints and to accommodate anticipated access needs for Members and other market participants. The Exchange has shared a single network with MIAX Pearl since MIAX Pearl became operational on February 6, 2017.[4] On the contrary, the Exchange and its other affiliate, MIAX Emerald, LLC (''MIAX Emerald'') operate on separate, unshared 10Gb ULL networks, since the launch of MIAX Emerald in March 2019.[5] The Exchange believes this separated network structure is also similar to at least one other national securities exchange group with multiple exchanges.[6] Operating two separate national securities exchanges on a single shared network provided certain benefits, such as streamlined connectivity to multiple exchanges, and simplified exchange infrastructure. However, doing so is no longer sustainable due to ever-increasing capacity constraints and current System [7] limitations. The network is not an unlimited resource. As described more fully below, the connectivity needs of Members and market participants increased every year since the launch of MIAX Pearl and the operations of the Exchange and MIAX Pearl on a single shared 10Gb ULL network is no longer feasible. This requires constant System expansion to meet Member demand for additional ports and 10Gb ULL connections, which has resulted in limited available System headroom (described in detail below). Therefore, the Exchange proposes to provide 10Gb ULL connectivity to the Exchange and MIAX Pearl on separate networks so that the Exchange and MIAX Pearl may increase their respective System capacities to meet the ongoing and anticipated connectivity needs of Members, prospective Members, and other market participants.

The Exchange began to operate on a single shared network with MIAX Pearl when MIAX Pearl commenced operations as a national securities

[35] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] *See* Press Release ''MIAX PEARL Successfully Launches Trading Operations'' (February 7, 2017), *available at https://www.miaxoptions.com/press-releases?_miax_filter_created%5Bmin%5D=2017-02-01+00%3A00%3A00&_miax_filter_created%5Bmax%5D=2017-02-28+23%3A59%3A59&actions=&_miax_filter_month=2&_miax_filter_year=2017; see also* Securities Exchange Act Release No. 79543 (December 13, 2016), 81 FR 92901 (December 20, 2016) (File No. 10–227) (order approving application of MIAX PEARL, LLC for registration as a national securities exchange).

[5] *See* Securities Exchange Act Release No. 87877 (December 31, 2019), 85 FR 738 (January 7, 2020) (SR–EMERALD–2019–39) (proposal to adopt connectivity fees without providing access to MIAX Emerald's affiliates, MIAX and MIAX Pearl, via a single shared connection).

[6] *See* the Physical Connectivity Fees sections of the Cboe BYX Exchange, Inc. (''BYX''), Cboe BZX Exchange, Inc. (''BYX''), Cboe EDGA Exchange, Inc. (''EDGA''), and Cboe EDGX Exchange, Inc. (''EDGX'', collectively with BYX, BZX, and EDGA, the ''Cboe Equity Exchanges'') equity fee schedules (not providing that a single port provides connectivity to each of Cboe Equity Exchanges).

[7] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

exchange on February 7, 2017.[8] The Exchange and MIAX Pearl have operated on a single shared network to provide Members with a single convenient set of access points for both exchanges. Both the Exchange and MIAX Pearl offer two methods of connectivity, 1Gb and 10Gb ULL connections. The 1Gb connection services are supported by a discrete set of switches providing 1Gb access ports to Members. The 10Gb ULL connection services are supported by a second and mutually exclusive set of switches providing 10Gb ULL access ports to Members. Today, both the 1Gb and 10Gb ULL shared extranet ports allow Members to use one connection to access both exchanges, namely their trading platforms, market data systems, test systems, and disaster recovery facilities.

As stated above, the shared network is not an unlimited resource and its expansion is constrained by MIAX's and MIAX Pearl's ability to provide fair and equitable access to all market participants of both markets. The Exchange and MIAX Pearl continue to be able to meet the access demands of new subscribers and satisfy the ongoing access demands of existing subscribers. However, over time, due to the ever-increasing connectivity demands, the Exchange now finds it necessary to bifurcate 10Gb ULL connectivity to the Exchange's and MIAX Pearl's Systems and networks to be able to continue to meet ongoing and future 10Gb ULL connectivity and access demands. Currently, the Exchange maintains sufficient headroom to meet ongoing and future requests for 1Gb connectivity. Therefore, the Exchange does not propose to alter 1Gb connectivity and will continue to provide 1Gb connectivity over a shared network and provide access to both the Exchange and MIAX Pearl over a single 1Gb connection.

The Exchange has two categories of Members: Market Makers [9] and Electronic Exchange Members [10] (''EEMs''). 10Gb ULL connectivity is predominantly used by Market Makers, latency sensitive liquidity removers, or those that require higher throughput (*i.e.,* greater than 1Gb). 1Gb connectivity is predominately used by EEMs who are less latency sensitive and tend to utilize a limited number of 1Gb connections. These EEMs will continue to be able to use that single 1Gb connection to access both the Exchange and MIAX Pearl. Certain EEMs use 10Gb ULL connectivity, primarily where that EEM also acts as a Market Maker either on the Exchange and/or MIAX Pearl and leverages that 10Gb ULL connection to access both exchanges. Service bureaus [11] also purchase 10Gb ULL connectivity and resell that connectivity to market participants who may not have direct connectivity to the Exchange.

Unlike the switches that provide 1Gb connectivity, the switches that provide 10Gb ULL connectivity have experienced a significant decrease in the availability for additional 10Gb ULL connections on each switch. This is mostly driven by the connectivity demands of latency sensitive Members (*e.g.,* Market Makers and liquidity removers) that seek to maintain connectivity across multiple 10Gb ULL switches. Such Members do not typically use a shared 10Gb ULL connection to reach both the Exchange and MIAX Pearl due to related latency concerns. Instead, those Members maintain dedicated separate 10Gb ULL connections for the Exchange and separate dedicated 10Gb ULL connections for MIAX Pearl. This results in a much higher 10Gb ULL usage per switch by those Members on the existing shared 10Gb ULL network than would otherwise be needed if the Exchange and MIAX Pearl had their own dedicated 10Gb ULL networks, similar to that provided by other exchanges, including the Exchange's and MIAX Pearl's affiliate, MIAX Emerald. Separation of the Exchange and MIAX Pearl 10Gb ULL networks would naturally lend itself to reduced 10Gb ULL port consumption on each switch and, therefore, increased 10Gb ULL port availability for current Members and new Members.

To date, the Exchange and MIAX Pearl have continued to add switches to meet ongoing demand for 10Gb ULL connectivity. Unfortunately, that is no longer sustainable because simply adding additional switches to expand the current shared 10Gb ULL network would not continue to alleviate the issue of limited available port connectivity. While it would result in a gain in overall port availability, the existing switches in use would continue to suffer from lack of port headroom given many latency sensitive Members' needs for a presence on each switch to reach both the Exchange and MIAX Pearl. This is because those latency sensitive Members seek to have a presence on each switch to maximize the probability of experiencing the best network performance. Those Members routinely decide to rebalance the amount of orders and/or messages over its various connections to ensure each connection is operating with maximum efficiency. Simply adding switches to the extranet is ineffective at resolving the port availability concerns on the existing extranet since many of the latency sensitive Members are unwilling to relocate their connections to a new switch due to the potential detrimental performance impact. As such, the impact of adding new switches and rebalancing ports is not effective. The Exchange has, therefore, found that ongoing and continued rebalancing once additional switches are added has had, and will continue to have, a diminishing return on increasing available 10Gb ULL connectivity.

The below example illustrates how the bifurcation of the 10Gb ULL network would lead to expanded access. This example is for illustrative purposes only. Assume the shared network includes ten (10) switches and each switch provides access via 24 10Gb ULL connections. For each switch, the numerator represents the number of consumed 10Gb ULL connections while the denominator represents the number of available 10Gb ULL connections. The ''Shared Network'' row illustrates the number of consumed and available 10Gb ULL connections on each switch. The usage of the ports on the shared network are roughly distributed 50% to MIAX Options and 50% to Pearl Options. The ''Single MIAX Network'' and ''Single Pearl Network'' rows illustrate how the Exchange may double its available 10Gb ULL connections

[8] *See* Securities Exchange Act Release No. 80061 (February 17, 2017), 82 FR 11676 (February 24, 2017) (establishing MIAX Pearl Fee Schedule and establishing that the MENI can also be configured to provide network connectivity to the trading platforms, market data systems, test systems, and disaster recovery facility of the MIAX Pearl's affiliate, MIAX, via a single, shared connection).

[9] The term ''Market Maker'' or ''MM'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of the Exchange Rules. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[10] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[11] Service bureaus provide access to market participants to submit and execute orders on an exchange. On the Exchange, a Service Bureau may be a Member. Some Members utilize a Service Bureau for connectivity and that Service Bureau may not be a Member. Some market participants utilize a Service Bureau who is a Member to submit orders. Only Members may submit orders or quotes through 10Gb ULL connectivity.

simply by bifurcating the Shared 10Gb ULL network.

Switch	1	2	3	4	5	6	7	8	9	10
Shared Network	18/6	19/5	16/8	17/7	20/4	16/8	15/9	17/7	13/11	14/10
Single MIAX Network	9/15	9/15	8/16	8/16	10/14	8/16	7/17	8/16	6/18	7/17
Single Pearl Network	9/15	10/14	8/16	9/15	10/14	8/16	8/16	9/15	7/17	7/17

Based on its experience and expertise, the Exchange finds the most practical way to increase connectivity availability on its switches is to bifurcate the existing 10Gb ULL networks for the Exchange and MIAX Pearl by migrating the exchange's connections from the shared network onto their own set of switches. If a number of new Members seek to participate in high frequency activity and require a port on each switch, they could quickly consume the available ports on the shared extranet. Further, if an existing Member seeks to temporarily double their port connections while they transition to new network and/or server infrastructure, they could consume the remaining available ports on the shared extranet. The Exchange, therefore, believes it is necessary and most efficient to bifurcate the Exchange and MIAX Pearl 10Gb ULL networks so that both exchanges can continue to satisfy ongoing and anticipated future requests for additional connectivity allowing it to provide meaningful and fair access to each market.

Bifurcating the Exchange and MIAX Pearl 10Gb ULL networks provides benefits beyond the ability to continue to meet ongoing and anticipated connectivity demands. For example, today if there is a problem on the shared network, it could impact the operation of both the Exchange and MIAX Pearl. As national securities exchanges, the Exchange and MIAX Pearl are subject to Regulation Systems Compliance and Integrity (''Reg. SCI'').[12] Reg. SCI Rule 1001(a) requires that the Exchange and MIAX Pearl establish, maintain, and enforce written policies and procedures reasonably designed to ensure (among other things) that their Reg. SCI systems have levels of capacity adequate to maintain the Exchange's and MIAX Pearl's operational capabilities and promote the maintenance of fair and orderly markets.[13] By separating the 10Gb ULL networks, any potential system issue would be limited to one exchange, narrowing the impact and preventing unnecessary systems disruptions on the other exchange. Bifurcating the networks supports the Reg. SCI obligations for MIAX and MIAX Pearl in this regard by limiting any potential future risk of a systems issue to one exchange and not impacting the operations or market participants of the other exchange. Bifurcating the networks also allows each exchange to evolve separately, potentially by using different technology to cater to the unique demands of each exchange and their market participants to meet future needs.

The Exchange again notes that operating affiliated exchanges' over separate networks is not new or novel. For example, the Exchange's affiliate, MIAX Emerald, currently operates on a separate network.[14] The Exchange notes that at least one other group of affiliated exchanges operate on separate networks.[15]

The Exchange will file a separate proposal with the Commission pursuant to Section 19(b)(3)(A)(ii) of the Act[16] to: (i) set forth the applicable fees for the bifurcated 10Gb ULL network; (ii) remove provisions in the Exchange fee schedule that provides for a shared 10Gb ULL network; and (iii) specify that only the 1Gb network connection will continue to be shared by both the Exchange and MIAX Pearl. The Exchange will not bifurcate the 10Gb ULL network until it files a proposal to set forth the applicable fees for immediate effectiveness pursuant to 19(b)(3)(A)(ii) of the Act.[17]

Implementation

Due to the technological changes associated with this proposed change, the Exchange expects to bifurcate the Exchange and MIAX Pearl networks in the first quarter of 2023, currently anticipated to be January 23, 2023. The Exchange issued a Trading Alert on August 12, 2022 publicly announcing the planned network change and implementation plan and dates to provide market participants adequate time to prepare.[18] Any changes to the January 23, 2023 implementation date would be announced in a separate alert.

2. Statutory Basis

The Exchange believes that its proposal to bifurcate 10Gb ULL connectivity in the System networks for the Exchange and MIAX Pearl are consistent with 6(b) of the Act[19] in general, and furthers the objectives of 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that its proposal is consistent with the requirements under 6(b)(5)[20] of the Act that the Exchange's proposed changes remove impediments to and perfect the mechanism of a free and open market and a national market system. Operating affiliated exchanges on their own dedicated, separate networks is not new or novel. The Exchange notes that it and its affiliate, MIAX Emerald, currently operate on separate networks.[21] The Exchange is also aware of at least on other group of affiliated exchanges also operate on separate networks.[22]

The Exchange began to operate on a single shared network with MIAX Pearl when MIAX Pearl commenced operations as a national securities exchange on February 7, 2017.[23] This shared network is not an unlimited resource and its expansion is constrained by its ability to provide fair and equitable access to all market participants. Due to the ever-increasing

[12] 17 CFR 242.1000–1007.

[13] 17 CFR 242.1001(a).

[14] *See supra* note 5.

[15] *See supra* note 6.

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

[17] *Id.*

[18] *See MIAX Options and MIAX Pearl Options—Announce planned network changes related to shared 10G ULL extranet,* issued August 12, 2022, *available at https://www.miaxoptions.com/alerts/2022/08/12/miax-options-and-miax-pearl-options-announce-planned-network-changes-related-0* (last visited November 17, 2022).

[19] 15 U.S.C. 78f(b).

[20] *Id.*

[21] *See supra* note 5.

[22] *See supra* note 6.

[23] *See* Securities Exchange Act Release No. 80061 (February 17, 2017), 82 FR 11676 (February 24, 2017) (establishing MIAX Pearl Fee Schedule and establishing that the MENI can also be configured to provide network connectivity to the trading platforms, market data systems, test systems, and disaster recovery facility of the MIAX Pearl's affiliate, MIAX, via a single, shared connection).

connectivity demands, the Exchange finds it necessary to bifurcate 10Gb ULL connectivity to the Exchange's and MIAX Pearl's Systems and networks to be able to continue to meet ongoing and future 10Gb ULL connectivity and access demands. Unlike switches for 1Gb connectivity, switches dedicated to 10Gb ULL connectivity have experienced a significant decrease in port headroom mostly driven by connectivity demands of latency sensitive Members that seek to maintain connectivity across multiple 10Gb ULL switches. Separation of the 10Gb ULL networks of the Exchange and MIAX Pearl would naturally lend itself to reduced port consumption and, therefore, increased port availability, allowing the Exchange to continue to meet ongoing and anticipated requests for 10Gb ULL connectivity. Therefore, the Exchange believes this proposal removes impediments to and perfects the mechanism of a free and open market and a national market system.

Further, the proposed changes will allow the Exchange and MIAX Pearl to adjust the connectivity and access to their Systems in order to ensure that both markets are able to provide consistent and fair access to their Members on non-discriminatory terms and ensure sufficient capacity and headroom in their Systems. The Exchange and MIAX Pearl constantly monitor their Systems' performance based on market conditions and the potential need to make adjustments based on customer demand. Accordingly, the Exchange's obligations under 6(b)(5) of the Act,[24] market participant demand, and market conditions are key drivers of the System's architecture and expansion and, thus, the Exchange believes simply adding more switches and not bifurcating the 10Gb ULL networks is not an appropriate mechanism to provide fair and open access to the Exchange and MIAX Pearl.

The Exchange and MIAX Pearl anticipate that they will continue to expand their Systems and provide Members and other market participants with additional access based on customer demand and in response to changing market conditions. The Exchange represents that any expansion or adjustments in the number of available switches for network access will be conducted in a similar manner that ensures fair access to its System. The Exchange will also continuously assess its connectivity options and availability to ensure that they meet the needs of all market participants seeking to access the Exchange and MIAX Pearl.

The Exchange believes that its proposal is consistent with the requirements under 6(b)(5) of the Exchange Act that the Exchange provide access on terms that are not unfairly discriminatory and that the rules of an Exchange promote just and equitable principles of trade.[25] The Exchange believes the proposed changes promote just and equitable principles of trade because the proposal to split the Exchange's and MIAX Pearl's shared 10Gb ULL network connectivity will apply equally to all market participants and Members of both exchanges. The proposed bifurcation of the Exchange and MIAX Pearl 10Gb ULL network connectivity will promote just and equitable principles of trade because it will allow the Exchange and MIAX Pearl to be able to continue to offer access to their Systems on terms that are not unfairly discriminatory by continuing to meeting ongoing and anticipated connectivity demands of all Members. The shared 10Gb ULL network is not an unlimited resource of either MIAX or MIAX Pearl and its expansion is constrained by its ability to provide fair and equitable access to all market participants. The Exchange believes this proposal will allow the Exchange and MIAX Pearl to continue to be able to meet the access demands of new 10Gb ULL network connectivity subscribers and satisfy the ongoing 10Gb ULL connectivity access demands of existing subscribers.

The Exchange believes its proposal to bifurcate the 10Gb ULL networks of the Exchange and MIAX Pearl is not designed to permit unfair discrimination between customers, issuers, brokers and dealers because the Exchange believes that bifurcating 10Gb ULL connectivity between the Exchange and MIAX Pearl is the most practical way to increase connectivity availability on existing switches, providing fair and consistent access to all Members and potential Members that require 10Gb ULL connectivity access. The proposed change would increase available 10Gb ULL connectivity to all market participants, including Market Makers, EEMs, and Service Bureaus, enabling the Exchange to continue to meet market participants' current and anticipated connectivity needs. The Exchange also notes that certain market participants may choose to not purchase a 10Gb ULL connection to both the Exchange and MIAX Pearl if they determine that purchasing connections to both exchanges is not in their business interests or financially beneficial. Similarly, Service Bureaus may also choose to not purchase a 10Gb ULL connection to both the Exchange and MIAX Pearl if they determine that there is not sufficient demand from their customers to connect to one or both exchanges. Other Members, particularly EEMs, may choose to purchase 1Gb connectivity instead and use that single connection to access both the Exchange and MIAX Pearl.

As described in the above example, if new or existing Members deem it necessary for them to utilize additional ports on each switch, those Members will quickly consume the remaining available ports, leaving very little or no additional ports open for other Members or new Members to gain access. Further, if an existing Member seeks to temporarily increase their 10Gb ULL ports connections while they transition to a new network and/or server infrastructure, they could consume the remaining available ports. In the Exchange's experience, these types of scenarios have become more frequent, leading to the Exchange's proposal to bifurcate the 10Gb ULL networks of the Exchange and MIAX Pearl to be able to continue to provide fair access to all market participants of both exchanges. The Exchange, therefore, believes its proposal promotes just and equitable principles of trade, removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general protects investors and the public interest because it will allow MIAX and MIAX Pearl to continue to satisfy ongoing and anticipated future requests for additional 10Gb ULL connectivity access to each market.

Lastly, the Exchange believes that its proposal is consistent with the Exchange's capacity obligations pursuant Regulation SCI.[26] Regulation SCI Rule 1001(a) requires that the Exchange and MIAX Pearl establish, maintain, and enforce written policies and procedures reasonably designed to ensure (among other things) that their Regulation SCI systems have levels of capacity adequate to maintain the Exchange's and MIAX Pearl's operational capabilities and promote the maintenance of fair and orderly markets.[27] The Exchange's proposal to separate the 10Gb ULL networks of the Exchange and MIAX Pearl would mean that any future potential System issue would be limited to only one exchange, narrowing the impact and preventing unnecessary Systems disruptions on the

[24] *See* 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

[26] 17 CFR 242.1000–1007.

[27] 17 CFR 242.1001(a).

other exchange. This protects investors and the public interest by potentially reducing market disruptions to either MIAX or MIAX Pearl, depending on the issue, as opposed to disrupting both markets from a single event on the shared network. The Exchange believes this proposal supports the Regulation SCI obligations for the Exchange and MIAX Pearl in by limiting any potential future risk of a systems issue to one exchange and not impacting the operations or market participants of the other exchange. Bifurcating the networks also allows each exchange to evolve separately, potentially by using different technology to cater to the unique demands of each exchange and their market participants to meet future needs.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition because the bifurcation of the Exchange and MIAX Pearl 10Gb ULL networks would affect all Members equally and ensure that the Exchange continues to be able to satisfy all connectivity requests from all Members as requested. The Exchange believes the proposed rule changes will not impose any burden on inter-market competition. In fact, the Exchange believes that not bifurcating the Exchange and MIAX Pearl networks could have an adverse impact on inter-market competition because not doing so could hamper the Exchange's ability to expand its network to meet ongoing and future connectivity demand, which could, in turn, limit its ability to compete for Memberships and order flow. Separating its 10Gb ULL network from MIAX Pearl would enable the Exchange to better compete with other exchanges by ensuring it can provide adequate connectivity to existing and new Members, which may increase in ability to compete for order flow and deepen its liquidity pool, improving the overall quality of its market. Lastly, the Exchange believes its proposal will not impose any burden on inter-market competition because it would allow the Exchange to operate on a dedicated network in the same manner as other affiliated exchanges who operate on dedicated networks separate from their affiliates.[28]

[28] *See supra* notes 5 and 6.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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 after the date of the filing, or such shorter time as the Commission may8 designate, it has become effective pursuant to 19(b)(3)(A) of the Act [29] and Rule 19b–4(f)(6) [30] 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 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–MIAX–2022–48 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–MIAX–2022–48. 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–MIAX–2022–48 and should be submitted on or before January 17, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

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[29] 15 U.S.C. 78s(b)(3)(A).

[30] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96555; File Nos. SR–DTC–2022–011; SR–FICC–2022–008; SR–NSCC–2022–013]

Self-Regulatory Organizations; The Depository Trust Company; Fixed Income Clearing Corporation; National Securities Corporation; Order Granting Proposed Rule Changes To Amend Liquidity Risk Management Framework To Include a New Section Describing the Process by Which FICC Would Designate Uncommitted Resources as Qualifying Liquid Resources and Make Other Changes

December 20, 2022.

On October 20, 2022, The Depository Trust Company (''DTC''), Fixed Income Clearing Corporation (''FICC''), and National Securities Clearing Corporation (''NSCC'') (each a ''Clearing Agency,'' and collectively, the ''Clearing Agencies''), filed with the Securities and Exchange Commission (''Commission'') proposed rule changes SR–DTC–2022–011, SR–FICC–2022–008, and SR–NSCC–2022–013 (the ''Proposed Rule Changes'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b-4 thereunder [2] to Amend the Clearing Agencies Liquidity Risk Management Framework adopted by the Clearing Agencies. The Proposed Rule Changes were published for comment in the **Federal Register**,[3] and the Commission has received no comments on the changes proposed therein. This order approves the Proposed Rule Changes.

I. Description of the Proposed Rule Changes

A. Background

The Clearing Agencies adopted the Liquidity Risk Management Framework (''Framework'') to set forth the manner in which they measure, monitor and manage the liquidity risks that arise in or are borne by each of the Clearing Agencies, including (i) the manner in which each Clearing Agency deploys their respective liquidity tools to meet its settlement obligations on an ongoing and timely basis, and (ii) each applicable Clearing Agency's use of intraday liquidity.[4]

B. Process by Which FICC Could Designate Uncommitted Liquidity Resources as QLR

The proposed changes to the Framework [5] would add a new section describing the process by which FICC could designate uncommitted liquidity resources as qualifying liquid resources (''QLR'').[6] FICC states that, at this time, it does not have uncommitted liquidity resources designated as QLR; [7] however, the proposed new section would allow FICC to have such QLR to the extent the requirements of Rule 17Ad–22(a)(14)(ii)(B) are followed.[8]

The proposed new section would provide that, in order to designate an uncommitted liquidity resource as a QLR, FICC would identify the properties of each financing arrangement, including the underlying collateral and the liquidity providers, determine the rigorous analysis that would be appropriate based on the nature of that liquidity resource, and conduct that analysis at least annually. The components and results of that analysis would be presented to the Board Risk Committee at least annually. When considering whether to designate the uncommitted resource as a QLR, the Board Risk Committee would determine if the uncommitted liquid resource is highly reliable under extreme but plausible market conditions consistent with Rule 17Ad-22(a)(14)(ii)(B) under the Act.[9]

C. Liquidity Resources That Are Not Designated as QLR

The proposed changes to the Framework would also clarify that FICC may have access to liquidity resources that are not designated as QLR. FICC states that it maintains uncommitted master repurchase agreements (''MRAs'') that can be utilized to finance via the repo market the securities in FICC's Clearing Funds and those purchased on behalf of a defaulting Member to raise funds.[10] According to FICC, the MRAs may be utilized as liquidity resources in the event of a Member default, even though they are not designated as QLR.[11] The proposed rule change provides that, on a weekly basis, FICC would perform a study to estimate the depth of the repo market under prevailing market conditions as well as a sample stress scenario to assess potential available liquidity in the event of default of the largest Member. Moreover, at least annually, FICC would conduct counterparty due diligence reviews that would assess each non-QLR liquidity provider's ability to provide liquidity to FICC under current market conditions and would provide a summary of these

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 96211 (Nov. 2, 2022), 87 FR 67527 (Nov. 8, 2022) (File No. SR–DTC–2022–011) (''DTC Notice''); Securities Exchange Act Release No. 96210 (Nov. 2, 2022), 87 FR 67516 (Nov. 8, 2022) (File No. SR–FICC–2022–008) (''FICC Notice''); Securities Exchange Act Release No. 96219 (Nov. 3, 2022), 87 FR 67721 (Nov. 9, 2022) (File No. SR–NSCC–2022–013) (''NSCC Notice'').

[4] *See* Securities Exchange Act Release No. 82377 (Dec. 21, 2017), 82 FR 61617 (Dec. 28, 2017) (SR–DTC–2017–004; SR–NSCC–2017–005; SR–FICC–2017–008).

[5] In addition to the proposed changes to the Framework, submitted as confidential Exhibit 5 to these Proposed Rule Changes, the Clearing Agencies submitted excerpts from their Liquidity Risk Management Procedures, submitted as confidential Exhibit 3 to these Proposed Rule Changes. The Clearing Agencies requested confidential treatment of Exhibits 3 and 5 pursuant to 17 CFR 240.24b–2.

[6] The Framework defines QLR consistent with the definition set forth in the Commission's rules. *See* 17 CFR 240.17Ad-22(a)(14). Rule 17Ad-22(a)(14) defines qualifying liquid resources to include, among other things, assets that are readily available and convertible into cash through prearranged funding arrangements, such as prearranged funding arrangements determined to be highly reliable even in extreme but plausible market conditions by the board of directors of the covered clearing agency following a review conducted for this purpose not less than annually. *Id.*

[7] *See* FICC Notice, *supra* note 3, 87 FR at 67516. FICC further states that, consistent with its existing processes, FICC would consider whether any uncommitted liquidity resources, including those that are designated as QLR, would require a proposed rule change with the Commission pursuant to Section 19(b)(1) of the Act, and the rules thereunder, or an advance notice with the Commission pursuant to Section 806(e)(1) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled the Payment, Clearing, and Settlement Supervision Act of 2010, and the rules thereunder. *See id.;* 15 U.S.C. 78s(b)(1); 12 U.S.C. 5465(e)(1).

[8] *See* FICC Notice, *supra* note 3, 87 FR at 67516; 17 CFR 240.17Ad–22(a)(14)(ii)(B).

[9] 17 CFR 240.17Ad-22(a)(14)(ii)(B). According to FICC, examples of the type of information that the Board Risk Committee could rely on in order to determine whether it would be appropriate to designate the proposed uncommitted resource as a QLR would include whether (i) FICC has identified securities that may be pledged pursuant to the proposed financing arrangement and that such securities are reasonably likely to be readily available for pledging and acceptable as collateral; (ii) FICC has reviewed the terms of the proposed financing arrangement to confirm such terms are current, appropriate and not expected to restrict FICC's use of the proposed financing arrangement; (iii) FICC has completed due diligence of each liquidity provider as required by Rule 17Ad-22(e)(7)(iv) under the Act; and (iv) FICC has developed procedures to test the proposed financing arrangement at least annually to confirm the liquidity providers are operationally able to perform their commitments and are familiar with the drawdown process, consistent with the requirements of Rule 17Ad-22(e)(7)(v) under the Act. *See* FICC Notice, *supra* note 3, 87 FR at 67517, n. 12; 17 CFR 240.17Ad-22(e)(7)(iv) and (v). In addition, FICC would include in the analysis presented to the Board Risk Committee recommendations and analyses of an independent third party that the proposed resource is highly reliable in extreme but plausible market conditions. *See* FICC Notice, *supra* note 3, 87 FR at 67517, n. 12. The Commission's review of the underlying procedures submitted as confidential exhibits, *see supra* note 5, is consistent with FICC's statements in this regard.

[10] *See* FICC Notice, *supra* note 3, 87 FR at 67517.

[11] *Id.*

reviews to the Board Risk Committee.[12] In addition, FICC would test any non-QLR annually with the respective liquidity providers to confirm that such liquidity providers are operationally able to perform their commitments and are familiar with the applicable process.

As a conforming change, the proposed changes would delete language referring to MRAs as QLR and add a sentence stating that FICC may count MRAs as QLR if the procedures for designating them described in I.B as such are followed. The proposed changes would also clarify that this section of the Framework regarding liquidity resources that are not designated as QLR applies specifically to FICC.

D. Descriptions of Due Diligence and Testing

The proposed changes would delete a stand-alone section on the due diligence and testing of liquidity providers in the Framework, move those descriptions of the due diligence and testing to the respective sections of the Framework where each liquidity resource is described, and clarify where testing would not be performed. The stand-alone section currently states that the Counterparty Credit Risk department (''CCR'') reviews the limits, outstanding investments, and collateral held (if applicable) at each investment counterparty. The proposed changes would (i) restate this language to make clear that CCR's review includes a financial analysis of each counterparty, the Clearing Agencies' investments at each counterparty, and any recommendations for changes in limits to these investments, and (ii) place the restated sentence in the section of the Framework related to the specific liquidity resource that CCR is surveilling.[13] The stand-alone section also references formal reviews on the reliability of QLR providers and specifically ascribes certain due diligence and review responsibilities to CCR. The proposed changes would describe CCR's obligations regarding liquidity providers in the appropriate section of the Framework related to the specific liquidity resource that CCR is surveilling. The proposed changes also indicate where another department, such as Treasury, is responsible for actions that the stand-alone section ascribes to CCR. For non-QLR liquidity resources, the proposed rule change would describe FICC's role in reviewing these resources.

In addition, the proposed changes would add language to the descriptions of DTC's and NSCC's QLR to reflect DTC's and NSCC's current practices of conducting surveillance of bank lenders to their committed credit facility, and testing the committed credit facility at least annually to confirm that the lenders, agents and respective Clearing Agency are operationally prepared to meet their obligations under the facility and are familiar with the borrowing process.

With respect to NSCC, the proposed changes would provide that, because the process for collecting Supplemental Liquidity Deposits (''SLD''), pursuant to NSCC Rule 4A, is the same process used for collecting required deposits to the NSCC Clearing Fund, and Members are aware of such process, no testing is required for purposes of Rule 17Ad–22(e)(7)(v) under the Act.[14] In addition, the proposed changes would state that NSCC conducts Member outreach with those Members whose liquidity exposure may require them to make SLD in the future.

The proposed changes would also make a correction to the description of DTC's Collateral Monitor. Currently, the Framework states that the Liquidity Risk Product Unit verifies that the Collateral Monitor will not become negative if the transaction is processed. Since DTC states that verification is done automatically,[15] the proposed rule change would correct the sentence to state that DTC performs this verification automatically.

E. Description of the Clearing Agencies' QLR

The proposed changes would also make certain clarifications regarding each Clearing Agency's QLR, although they would not change what resources are available as QLR.

With respect to FICC, the proposed changes would clarify that each FICC division has its own Clearing Fund that includes deposits of cash and delete language regarding the ability of FICC to borrow from the Clearing Fund that is already covered in the Rules of each division.[16] The proposed changes would also clarify that such cash deposits would be held at creditworthy commercial banks that provide same day access to funds. Moreover, the proposed changes would clarify that the rules-based committed Capped Contingency Liquidity Facility programs are determined for each FICC division per the division's respective Rules.[17] Further, the Framework would clarify that FICC's members are not considered ''liquidity providers'' with respect to their Clearing Fund deposits, with reference to Rules 17Ad–22(e)(7)(iv) and (v) under the Act.[18]

With respect to NSCC, the proposed changes would clarify the description of QLR by deleting language regarding the ability of NSCC to borrow from the Clearing Fund that is already covered in the NSCC Rules [19] and replacing ''medium- and long-term'' with ''senior'' (which covers both medium- and long-term) before ''unsecured notes'' to simplify terminology.[20]

The proposed changes would also clarify the descriptions of DTC's and NSCC's QLR by adding language on same day access to funds regarding deposits of DTC Participants Fund and NSCC Clearing Fund in creditworthy commercial banks. Moreover, the proposed changes would make clear that DTC Participants and NSCC Members, respectively, are not considered ''liquidity providers'' with respect to their DTC Participants Fund deposits and NSCC Clearing Fund deposits, with reference to Rules 17Ad–22(e)(7)(iv) and (v) under the Act.[21]

F. Technical Changes

The proposed changes include certain technical changes as follows:

- Make conforming and cross-reference changes in the Executive Summary;
- Delete a sentence that states that liquidity resources are maintained consistent with risk tolerances, whereas the correct statement is that liquidity resources are maintained consistent with Rule 17Ad–22(e)(7) under the Act,[22] which is already stated elsewhere in the Framework;
- Make conforming and cross-reference changes in the general section on ''Liquidity Resources;''

[12] Such due diligence would include reviews of relevant member financial metrics, results of operational testing, and relevant market data applicable to the type of securities being financed.

[13] The Clearing Agencies note that a sentence in the stand-alone section that refers to a review of each investment counterparty's deposit level at the Federal Reserve Bank of New York would not be retained because it reflects a drafting error (the Clearing Agencies are concerned with their deposits at the counterparties and not the counterparties' deposits at the Federal Reserve Bank of New York). *See* DTC Notice, *supra* note 3, 87 FR at 67529, n.14; FICC Notice, *supra* note 3, 87 FR at 67517, n.14; NSCC Notice, *supra* note 3, 87 FR at 67723, n.14.

[15] *See* DTC Notice, *supra* note 3, 87 FR at 67530.

[16] *See* FICC/GSD Rule 4, Section 5 and FICC/MBSD Rule 4, Section 5, *available at http://dtcc.com/legal/rules-and-procedures.*

[17] *See* FICC/GSD Rule 22A, Section 2a and FICC/MBSD Rule 17, Section 2a, *available at http://dtcc.com/legal/rules-and-procedures.*

[18] 17 CFR 240.17Ad–22(e)(7)(iv) and (v).

[19] *See* NSCC Rule 4, Section 12, *available at http://dtcc.com/legal/rules-and-procedures.*

[20] *See* NSCC Notice, *supra* note 3, 87 FR at 67723.

[21] 17 CFR 240.17Ad–22(e)(7)(iv) and (v).

[22] 17 CFR 240.17Ad–22(e)(7).

- Restate the first sentence in the section describing FICC's QLR for clarity;
- Remove cross-references and phrases referencing other sections of the Framework where such references are no longer correct;
- Add the word ''FICC'' to the end of a sentence where it was inadvertently deleted; and
- Renumber the last three sections of the Framework to account for the deletion of the section on due diligence/testing.

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act [23] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and rules and regulations thereunder applicable to such organization. After carefully considering the Proposed Rule Changes and confidential Exhibit 3,[24] the Commission finds that the Proposed Rule Changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to the Clearing Agencies. In particular, the Commission finds that the Proposed Rule Change is consistent with Sections 17A(b)(3)(F) [25] of the Act and Rule 17Ad–22(e)(7) thereunder.[26]

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act [27] requires, in part, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[28]

The proposed changes would update the Framework to (1) describe the process by which FICC would designate uncommitted liquidity resources as QLR; (2) clarify that FICC may have access to liquidity resources that are not designated as QLR; (3) delete the stand-alone section on due diligence and testing of liquidity providers, and instead add due diligence and testing descriptions where each liquidity resource is described; (4) clarify the description of FICC's QLR; (5) clarify the description of NSCC's and DTC's QLR, add language to reflect NSCC's and DTC's current due diligence and testing processes regarding their committed line of credit, and make a correction to the description of DTC's Collateral Monitor; and (6) make technical changes.

The Commission believes that these proposed changes will improve the clarity of descriptions of the Clearing Agencies' Framework and enable the Clearing Agencies to more effectively deploy their risk management tools to manage liquidity risks presented by their members. For example, the proposed changes will describe the specific process through which FICC could designate uncommitted resources as QLR, and this process would be designed to ensure that any uncommitted resource that is designated as QLR would be highly reliable in extreme but plausible market conditions. The proposed changes, therefore, would enhance the Clearing Agencies' liquidity risk management functions, which are designed help the Clearing Agencies maintain sufficient liquid resources to meet their potential funding obligations to timely settle outstanding transactions of a defaulting participant or family of affiliated participants. For these reasons, the Commission finds that the proposed changes are designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds in the custody and control of the Clearing Agencies consistent with the requirements of Section 17A(b)(3)(F) of the Act.[29]

B. Consistency With Rule 17Ad–22(e)(7)

Rule 17Ad–22(e)(7) under the Act [30] requires covered clearing agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to, among other things, effectively measure, monitor, and manage the liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum, meeting the requirements set forth in Rule 17Ad–22(e)(7).

The Commission believes that the proposed changes described above are consistent with the requirements of Rule 17Ad–22(e)(7). By clarifying FICC's process for designating uncommitted liquidity resources as QLR, the proposed changes are designed to ensure that any uncommitted resource that is designated as QLR would be highly reliable in extreme but plausible market conditions to be consistent with the requirements of Rule 17Ad–22(a)(14) under the Act,[31] thereby facilitating FICC's ability to hold QLR sufficient to meet its minimum liquidity resource requirements under Rule 17Ad–22(e)(7). Moreover, by identifying liquidity resources that are not QLR and providing various clarifications, the proposed changes would reduce ambiguity and thus assist risk management staff in the performance of their duties associated with the Clearing Agencies' compliance with Rule 17Ad–22(e)(7).

For these reasons, the Commission believes that proposed changes are consistent with Rule 17Ad–22(e)(7) under the Act.[32]

III. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Changes are consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act [33] and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act [34] that proposed rule changes SR–DTC–2022–011, SR–FICC–2022–008, and SR–NSCC–2022–013, be, and hereby are, *approved.*[35]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–28088 Filed 12–23–22; 8:45 am]

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[23] 15 U.S.C. 78s(b)(2)(C).

[24] *See supra* note 5.

[25] 15 U.S.C. 78q–1(b)(3)(F).

[26] 17 CFR 240.17Ad–22(e)(7).

[27] 15 U.S.C. 78q–1(b)(3)(F).

[28] *Id.*

[29] *Id.*

[30] 17 CFR 240.17Ad–22(e)(7).

[31] 17 CFR 240.17Ad–22(a)(14).

[32] 17 CFR 240.17Ad–22(e)(7).

[33] 15 U.S.C. 78q–1.

[34] 15 U.S.C. 78s(b)(2).

[35] In approving the proposed rule change, the Commission considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[36] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96550; File No. SR–FINRA–2022–032]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change Relating to Alternative Display Facility New Entrant

December 20, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 16, 2022, the Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. 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

FINRA is proposing to add IntelligentCross ATS (''IntelligentCross'') as a new entrant to the Alternative Display Facility (''ADF'').

IntelligentCross has prepared a summary of its policies and procedures regarding access to quotations in an NMS stock displayed on the ADF, and a summary of its proposed fees for such access. A copy of that summary is available on FINRA's website at *http://www.finra.org.*

The proposed rule change does not make any changes to the text of FINRA rules.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA 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. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. *Purpose*

FINRA is proposing to add a new entrant—IntelligentCross—to the ADF. The ADF is a quotation collection and trade reporting facility that provides ADF market participants (*i.e.,* ADF-registered market makers or electronic communications networks) [3] the ability to post quotations, display orders and report transactions in NMS stocks [4] for submission to the securities information processors (''SIP'') for consolidation and dissemination to vendors and other market participants. In addition, the ADF delivers real-time data to FINRA for regulatory purposes, including enforcement of requirements imposed by SEC Regulation NMS.

The ADF was initially approved by the Commission on July 24, 2002, in connection with Nasdaq's registration as a national securities exchange.[5] At that time, the ADF was approved for Nasdaq-listed securities for a nine-month pilot period to provide FINRA members with an alternative to the Nasdaq systems for reporting quotations and transactions in Nasdaq UTP Plan securities.

In 2005, the Commission adopted Regulation NMS, which included an order protection rule [6] that established trade-through protection for all NMS stocks.[7] Since the ADF is a display-only facility, a market participant would have to access the actual ADF participant that posted the protected quotation on the ADF in order to comply with the Order Protection Rule.[8] In the NMS Adopting Release, the Commission noted that market participants could potentially access an ADF participant either through direct access or through a private network.[9]

Given that market participants could be required to access multiple ADF participants to comply with the Order Protection Rule, the Commission formulated Rule 610 under SEC Regulation NMS to ensure that market participants would be afforded ''fair and efficient access'' to such trading centers.[10] Accordingly, Rule 610 requires that a trading center displaying quotations in an NMS stock through an SRO display-only facility (such as the ADF) ''provide a level and cost of access to such quotations that is substantially equivalent to the level and cost of access to quotations displayed by SRO trading facilities in that stock.'' [11] Rule 610 also requires that a trading center displaying quotations in an NMS stock through an SRO display-only facility not impose unfairly discriminatory terms that prevent or inhibit any person from obtaining efficient access to such quotations through a member, subscriber, or customer of the trading center.[12]

In articulating this standard, the Commission noted that the level and cost of access would ''encompass both (1) the policies, procedures, and standards that govern access to quotations of the trading center, and (2) the connectivity through which market participants can obtain access and the cost of such connectivity.'' [13] The nature and cost of connections for market participants seeking to access an ADF participant's quotations would need to be substantially equivalent to the nature and cost of connections to SRO trading facilities.[14]

In evaluating whether ADF participants are meeting the access standards under Rule 610 of Regulation NMS, *i.e.,* that the cost of accessing an ADF participant is substantially equivalent to the cost of accessing an SRO trading facility, the Commission stated that the NASD (now FINRA) would act as a gatekeeper in this process. As such, FINRA would be required to submit a proposed rule change pursuant to 19(b) of the Act to add a new ADF participant.[15] There has not been an active quoting participant on the ADF since the first quarter of 2015. Consistent with the requirements of Rule 610 of Regulation NMS and the NMS Adopting Release, FINRA is submitting this proposed rule change so

[3] *See* FINRA Rule 6220(a)(3).

[4] *See* 17 CFR 242.600.

[5] *See* Securities Exchange Act Release No. 46249 (July 24, 2002), 67 FR 49822 (July 31, 2002) (Order Approving File No. SR–NASD–2002–97); *see also Notice to Members* 02–45 (August 2002).

[6] Rule 611 of Regulation NMS (the ''Order Protection Rule'') provides that a trading center ''shall establish, maintain, and enforce written policies and procedures that are reasonably designed to prevent trade-throughs on that trading center of protected quotations in NMS stocks'' that do not fall within one of the exceptions set forth in the rule. *See* 17 CFR 242.611.

[7] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37501 (June 29, 2005) (''NMS Adopting Release'').

[8] *See* NMS Adopting Release, *supra* note 7 at 37541.

[9] *See* NMS Adopting Release, *supra* note 7 at 37543.

[10] *See* NMS Adopting Release, *supra* note 7 at 37549.

[11] 17 CFR 242.610(b)(1).

[12] 17 CFR 242.610(b)(2).

[13] *See* NMS Adopting Release, *supra* note 7 at 37549.

[14] *See* NMS Adopting Release, *supra* note 7 at 37549.

[15] *See* NMS Adopting Release, *supra* note 7 at 37549.

that IntelligentCross may become an ADF market participant.

Overview of IntelligentCross

IntelligentCross is an NMS stock ATS operating pursuant to an effective Form ATS–N and is required to comply with the conditions of the Regulation ATS exemption.[16] IntelligentCross ASPEN operates three separate limit order books with optional display capability distinguished by different fee structures—the ASPEN fee/fee limit order book, ASPEN maker/taker limit order book, and ASPEN taker/maker limit order book.[17] All three ASPEN order books act independently of each other; therefore, orders resting in one book do not rest on or interact with orders resting in another book.[18] The ASPEN Fee/Fee limit order book would be the only order book displaying orders on the ADF. All activity on IntelligentCross is identified and reported under the ''INCR'' market participant identifier (or ''MPID'').[19]

As set forth in IntelligentCross' summary, IntelligentCross only permits registered broker-dealers to be subscribers to IntelligentCross, and subscribers can interact with ASPEN Fee/Fee using conventional order types. Specifically, ASPEN Fee/Fee accepts limit orders with optional display instructions, immediate or cancel orders, and pegged orders (which are treated as regular orders with an automated repricing to the national best bid or offer (''NBBO'')).[20] Only ASPEN Fee/Fee will accept incoming intermarket sweep orders (''ISOs'')[21] once it displays orders on the ADF.[22]

IntelligentCross has represented that ASPEN Fee/Fee utilizes a matching process that it has engineered to seek to maximize price discovery and provide an opportunity for investors to improve performance and achieve best execution. As set forth in its summary, ASPEN Fee/Fee establishes a matching schedule using an overnight optimization process that uses historical performance measurements from prior days' matches across all three IntelligentCross ASPEN books. Match schedules are defined by minimum/maximum time bands for each security, and these bands can have a minimum time of 150 microseconds and a maximum time of 900 microseconds (*i.e.,* the maximum time for scheduling a match event is capped at 900 microseconds). For example, on a particular day, the match event band for XYZ stock may have a minimum time of 450 microseconds and a maximum time of 600 microseconds. The time of the actual match event is randomized within the match event band throughout the course of the trading day. Any order for a security that arrives prior to a match event (and that has not been cancelled, become unmarketable, or repriced)[23] will be eligible to participate in the next match event for that security.[24] ASPEN Fee/Fee's matching process operates on a near-continuous basis throughout the day.[25] Match events are scheduled continuously while ASPEN Fee/Fee's order book is in a ''matchable state'' (*i.e.,* there is an order on each side eligible to match).[26]

For each match event time, ASPEN Fee/Fee retrieves the NBBO and processes all the orders that have arrived and have not been cancelled in price-time priority (and, at each price level, displayed orders will have priority over non-displayed orders).[27] No subscriber (or non-subscriber accessing IntelligentCross through a subscriber) is given any priority through the matching process and the matching process is blind to the identity of the subscriber. Any matches are immediately reported to subscribers and the SIPs via a FINRA trade reporting facility and disseminated on IntelligentCross' market data feed.[28] ASPEN Fee/Fee automatically updates its quotations, and all quotation updates, including those due to new or cancelled orders, are immediate. As set forth in its summary, IntelligentCross will maintain policies and procedures designed for ASPEN Fee/Fee to maintain a linkage with the ADF and to transmit to the ADF for display the best priced orders entered by subscribers. As stated in its summary, IntelligentCross believes that including ASPEN Fee/Fee's displayed liquidity as a protected quote on the ADF will provide market participants an opportunity to improve performance and achieve best execution for their customers.

Regulation NMS Requirements for Protected Quotations

Rule 611 of Regulation NMS provides for price protection across markets against trade-throughs for ''automated quotations'' in NMS stocks.[29] Under Regulation NMS, an ''automated

[16] *See* Form ATS–N Filings and Information page on the Securities and Exchange Commission's website, at *https://www.sec.gov/divisions/marketreg/form-ats-n-filings.htm.*

[17] For purposes of this filing, ''IntelligentCross ASPEN'' refers collectively to the three ASPEN limit order books. ''ASPEN Fee/Fee'' refers to the ASPEN fee/fee limit order book with optional display capability that would display orders on the ADF. In addition to IntelligentCross ASPEN, IntelligentCross also operates a midpoint book that only accepts non-displayed midpoint orders, which is distinct from and does not interact with any of the three ASPEN limit order books.

[18] ASPEN Fee/Fee publishes displayed prices in over 6,900 securities. As set forth in IntelligentCross' summary, any orders entered into IntelligentCross will default to the ASPEN Fee/Fee book (aside from midpoint peg orders, which will default to the midpoint book). A subscriber who wishes to trade in the ASPEN maker/taker or taker/maker books must affirmatively identify those books when entering their order.

[19] IntelligentCross recognizes that, should trading reach the applicable thresholds under Rule 301(b)(3) or Rule 301(b)(5) of Regulation ATS, IntelligentCross would be required to comply with the applicable requirements of Regulation ATS. *See, e.g., 17 CFR 242.301(b)(3) and (b)(5).* In addition, IntelligentCross acknowledges that other regulatory obligations may become applicable in the future depending upon changes to the platform or its volume (*e.g.,* obligations under Regulation Systems Compliance and Integrity). *See 17 CFR 242.1000* through 242.1007.

[20] As set forth in IntelligentCross' summary, only limit orders and primary peg orders (with or without a limit price) are eligible to be displayed on the ASPEN Fee/Fee book, and therefore on the ADF.

[21] 17 CFR 242.600(b)(38).

[22] As set forth in its summary, IntelligentCross has represented that ASPEN Fee/Fee will be the only ASPEN order book that will accept ISOs.

[23] As set forth in its summary, IntelligentCross has represented that situations may occur where an incoming order on ASPEN Fee/Fee may not execute against a resting order at match event time such as where: an existing resting order cancels prior to the next match event; an incoming order is canceled prior to the next match event; the NBBO moves between the time an order is received and the next match event takes place, making either the incoming order or the resting order non-marketable; or the NBBO changed before the next match event and pegged orders were repriced to the new NBBO, making the incoming order or the resting pegged order non-marketable.

[24] Both sides of the trade (buyers and sellers) are on equal footing for the next scheduled match event, while maintaining full control of their orders, *i.e.,* both sides can cancel or update their orders at any time prior to the match. The ASPEN Fee/Fee book will automatically update its quotations, and all quotation updates, including those due to new or cancelled orders, are immediate.

[25] A list of illustrative use cases of IntelligentCross' matching process is included in the IntelligentCross Form ATS–N. *See supra* note 16.

[26] If there are no orders for a stock in the book, no match event will be scheduled. An incoming order that will make the book potentially matchable will trigger a scheduling of a match event if one has not already been scheduled.

[27] IntelligentCross uses a combination of SIP and proprietary direct feeds from national securities exchanges to determine the NBBO and protected quotes (*e.g.,* for trade through purposes), and to price executions.

[28] IntelligentCross has represented that displayed orders from all three ASPEN order books are available in the IQX market data feed. Each of the ASPEN books have individualized data feeds; as such, subscribers to the IQX market data feed can choose to consume data from whichever ASPEN books they choose through separate feed identifiers. IntelligentCross has represented that the ASPEN Fee/Fee book will provide any quotes or quote updates to the ADF no later than what is disseminated via the IQX market data feed.

[29] 17 CFR 242.600(b)(6). *See also* 17 CFR 242.600(b)(70) and (71).

quotation'' is one that, among other things, can be executed ''immediately and automatically'' against an incoming IOC order.[30] As stated above, IntelligentCross has represented that ASPEN Fee/Fee's matching engine operates near-continuously and that, when a new order arrives in the ASPEN Fee/Fee book, it will participate in the next scheduled match event by interacting with existing orders in the order book within a maximum time capped at 900 microseconds.

FINRA believes that quotations displayed on ASPEN Fee/Fee would meet the definition of an ''automated quotation'' under Regulation NMS. FINRA notes that, in 2016, the Commission interpreted Regulation NMS's immediacy requirement to allow for ''an intentional access delay that is *de minimis—i.e.,* a delay so short as to not frustrate the purposes of Rule 611 by impairing fair and efficient access to an exchange's quotations.'' [31] The Commission stated that ''[i]n the context of Regulation NMS, the term 'immediate' does not preclude all intentional delays regardless of their duration, and such preclusion is not necessary to achieve the objectives of Rule 611. As long as any intentional delay is *de minimis—i.e.,* does not impair fair and efficient access to an exchange's protected quotations—it is consistent with both the text and purpose of Rule 611.'' [32] SEC staff has further stated that ''consistent with the Commission's interpretation regarding automated quotation under Rule 600(b)(3) of Regulation NMS, delays of less than a millisecond are at a *de minimis* level that would not impair fair and efficient access to a quotation, consistent with the goals of Rule 611.'' [33]

FINRA notes that ASPEN Fee/Fee's matching process includes match events that occur at pre-defined increments within 150 microseconds to 900 microseconds of order arrival, which is less than one millisecond. FINRA believes that this *de minimis* delay provides for an ''immediate'' execution of incoming orders while ASPEN Fee/Fee's order book is in a matchable state. In addition, FINRA believes that ASPEN Fee/Fee's matching process executes orders automatically because, as set forth in its summary, IntelligentCross represented that the quotations displayed on ASPEN Fee/Fee are handled on an automated basis and that there is no human discretion in determining any action taken with respect to an order after the order is received.[34]

As discussed in IntelligentCross' summary and above,[35] situations may occur where an incoming order may not execute against a resting order at match event time, such as when an existing resting order cancels prior to the next match event; an incoming order is canceled prior to the next match event; the NBBO moves between the time an order is received and the next match event takes place, making either the incoming order or the resting order non-marketable; or the NBBO changed before the next match event and pegged orders were repriced to the new NBBO, making the incoming order or the resting pegged order non-marketable.

For example, assume the NBBO in XYZ stock is $10.00 × $10.01 at 9:30:00.000000 and ASPEN Fee/Fee is displaying a limit order to buy at $10.00. At 9:30:00.000010, ASPEN Fee/Fee receives an order to sell at $10.00. At 9:30:00.000020, the displayed limit order to buy is cancelled. At 9:30:00.000040—the time of the next scheduled match event in XYZ stock—no match event occurs as there are no two matchable orders at that time. The same result would occur in this example if a subscriber sent a sell order that would have interacted with the buy limit order but then cancels their sell order at any time prior to the next scheduled match event.

As another example, assume the NBBO in XYZ stock is $10.00 × $10.01 at 9:30:00.000000 and ASPEN Fee/Fee is displaying a limit order to buy at $10.00. At 9:30:00.000010, ASPEN Fee/Fee receives a sell order to sell at $10.00. At 9:30:00.000040—the time of the next scheduled match event in XYZ stock—the NBBO has changed and is now 10.01 × 10.02. A match will not occur because ASPEN Fee/Fee will not execute a match outside of the NBBO (*i.e.,* the resting order is now non-marketable) except that, as set forth in IntelligentCross' summary, if the sell order were an ISO, an execution would occur at $10.00 at the scheduled match event time.

Finally, assume that the NBBO in XYZ stock is $10.00 × $10.01 at 9:30:00.000000 and ASPEN Fee/Fee is displaying a primary peg buy order with a limit of $10.00. At 9:30:00.000010, ASPEN Fee/Fee receives a sell order to sell at $10.00. At 9:30:00.000040, the time of the next scheduled match event in XYZ stock, the NBBO is now $9.99 × $10.01. A match will not occur because the pegged order follows the NBBO and gets repriced to the current NBBO of $9.99. If the NBBO had moved to $10.01 × $10.02, ASPEN Fee/Fee's primary peg would not reprice as it is limited to $10.00, and a match also would not occur.

IntelligentCross has represented that non-match events on ASPEN Fee/Fee occur in a minority of cases. Year-to-date (through the end of November 2022), IntelligentCross represented that 4.2 percent of potential matches on ASPEN Fee/Fee did not complete because a displayed order was canceled, and 4.7 percent of potential matches on ASPEN Fee/Fee did not complete because the NBBO changed and at least one of the sides became non-marketable. In such cases, IntelligentCross represented that subscribers exercised their right to change their orders or, in the case of pegged orders, instructed that their orders be changed in reaction to NBBO changes.

Level of Cost and Access to ASPEN Fee/Fee Quotations

Regulation NMS Rule 610(b) requires that any trading center that displays quotations in an NMS stock through an SRO display-only facility must provide a level and cost of access to such quotations that is substantially equivalent to the level and cost of access to quotations displayed by SRO trading facilities in that stock.[36] Regulation NMS Rule 610(b) further requires that any trading center that displays quotations in an NMS stock through an SRO display-only facility shall not impose unfairly discriminatory terms that prevent or inhibit any person from obtaining efficient access to such quotations through a member, subscriber, or customer of the trading center. The cost of accessing the quotation of a trading center may consist of several distinct costs, such as port fees, market data fees, general connectivity fees, and transaction fees. As set forth in its summary, IntelligentCross represented that it believes the level and cost of access to its quotations complies with Rule 610 of

[30] 17 CFR 242.600(b)(6).

[31] Commission Interpretation Regarding Automated Quotations Under Regulation NMS, Securities Exchange Act Release No. 78102 (June 17, 2016), 81 FR 40785, 40792 (June 23, 2016).

[32] *See supra* note 31.

[33] *See* Staff Guidance on Automated Quotations under Regulation NMS available at *https://www.sec.gov/divisions/marketreg/automated-quotations-under-regulation-nms.htm.*

[34] The Commission has stated that, for a quotation ''[t]o qualify as 'automatic,' no human discretion in determining any action taken with respect to an order may be exercised after the time an order is received,'' and ''a quotation will not qualify as 'automated' if any human intervention after the time an order is received is allowed to determine the action taken with respect to the quotation.'' *See* Regulation NMS Adopting Release, *supra* note 7 at 37519 and 37534.

[35] *See supra* note 23.

[36] 17 CFR 242.610(b).

Regulation NMS and will be substantially equivalent to the cost of access to quotations displayed by SRO trading facilities in that stock and the costs to connect to any other trading center, such as an exchange. IntelligentCross also represented that it utilizes a matching process that provides fair and efficient access to its quotations.[37]

Specifically, as described in its summary, IntelligentCross utilizes a fee/fee pricing model for activity on ASPEN Fee/Fee where both sides are charged the same fee for transactions.[38] The base rate charged by IntelligentCross is $0.0008 per share for each side of a transaction on ASPEN Fee/Fee.[39] IntelligentCross' fee schedule for subscribers is published in the IntelligentCross Form ATS–N and pricing is subject to change with advance notice provided to subscribers. Eligible displayed orders are published via a free market data feed (''IQX market data feed'').[40] In comparison, market data fees vary by exchange, with some exchanges charging fees that range from under $500 per month to $2500, and some exchanges charging $4000 for external distribution.[41]

Firms wishing to access liquidity on ASPEN Fee/Fee may connect in a variety of ways. Firms that are IntelligentCross subscribers connect to ASPEN via a Financial Information Exchange (''FIX'') connection. Such access is available to subscribers through an internet protocol address via communications that are compliant with the FIX application programming interface (''API'') provided by IntelligentCross. IntelligentCross does not accept orders via any other forms of communication (*e.g.,* telephone, email, instant message). IntelligentCross allows a subscriber to determine its level of connectivity and does not tier or discriminate among subscribers.

IntelligentCross has represented that it does not charge connectivity fees to its subscribers. Subscribers wanting to connect directly to IntelligentCross' user acceptance testing and production servers must establish cross-connects with the servers of IntelligentCross' co-location and network provider, Pico Quantitative Trading, or connect through other network service providers that have a presence in the Equinix NY4 data center. IntelligentCross has represented that it is not involved in the installation of cross-connects; thus, subscribers must establish a relationship directly with the network service provider, NY4.[42] IntelligentCross has represented that it does not currently charge connectivity fees to access ASPEN and has offered to pay for certain of subscribers' cross-connect fees at NY4. IntelligentCross also currently pays for one primary connection and one back-up connection, and any direct subscriber is eligible for this payment. IntelligentCross' network provider and other similar network providers may charge fees relating to connectivity. IntelligentCross has represented that any such connectivity fees would be substantially equivalent to the costs to connect to any other trading center, such as an exchange.[43]

As stated in its summary, IntelligentCross also has established and maintains policies and procedures related to periodic system capacity reviews and tests to ensure future capacity, as well as policies and procedures to identify potential weaknesses and reduce the risks of system failures and threats to system integrity. For purposes of displaying orders through the ADF, IntelligentCross' policies and procedures also require continuous monitoring of ASPEN's connections with an SRO display-only facility and, in the event that ASPEN loses connection with the ADF, IntelligentCross has contingency plans in place, including removing (*i.e.,* ''zeroing out'') all quotes previously published by the system to the ADF and notifying its subscribers of such interruption.

If the Commission approves the proposed rule change, the effective date of the proposed rule change will be the date of Commission approval.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of 15A(b)(6) of the Act,[44] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest, 15A(b)(9) of the Act,[45] which requires that FINRA rules not impose any burden on competition that is not necessary or appropriate, and 15A(b)(11) of the Act,[46] which requires among other things that FINRA rules include provisions governing the form and content of quotations relating to securities sold otherwise than on a national securities exchange which may

[37] With respect to the requirement that the nature and cost for market participants seeking to access an ADF Trading Center be substantially equivalent to the nature and cost of connection to SRO trading facilities, FINRA notes that the Commission stated in the NMS Adopting Release that this requirement does not apply on an absolute basis, but rather applies on a per-transaction basis to reflect the costs relative to the ADF participant's trading volume. *See* NMS Adopting Release, *supra* note 7 at 37549 n.449. Based on IntelligentCross' representations, FINRA believes that IntelligentCross' proposed level and cost of access to quotations on ASPEN Fee/Fee is substantially equivalent to the level and cost of access to quotations displayed by an SRO trading facility, both in absolute and relative terms.

[38] IntelligentCross has represented that ASPEN Fee/Fee subscribers can pay lower fees through (1) a ''Total Composite Volume Incentive'' based on the total market volume in all NMS Stocks reported to the consolidated tape and (2) an ''Active Order Incentive'' which is based on a per symbol basis and the percent that is marketable. The ASPEN Fee/Fee and midpoint order books will follow the same fee schedule, and shares traded will aggregate for volume pricing tiers. The ASPEN maker/taker and ASPEN taker/maker orders books are charged independently.

[39] In comparison, Cboe BZX Exchange, Inc. assesses a $0.0030 charge per share for orders in securities priced $1 or above that remove liquidity. Investors Exchange LLC (''IEX'') assesses a fee of $0.0006 for removing displayed liquidity for orders in securities that are priced at or above $1, and MEMX LLC (''MEMX'') assesses a fee that ranges from $0.0029 to $0.0030 for removing displayed liquidity above $1.

[40] *See supra* note 28.

[41] IEX charges $500 for their Top of Book Quote and Last Sale (TOPS) real-time feed and $2,500 per month for its Depth of Book and Last Sale (DEEP) real-time feed. *See https://exchange.iex.io/resources/trading/fee-schedule/.* Cboe BYX Exchange, Inc. (''BYX'') charges a $250/month external distribution fee for BYX top-of-book data and a $1,000/month external distribution fee for BYX last sale data. *See https://www.cboe.com/us/equities/membership/fee_schedule/byx/.* MEMX charges a $2,000/month external distributor fee for its top-of-book data and a $2,000/month external distributor fee for last sale data. *See https://info.memxtrading.com/fee-schedule/.*

[42] Exchange port fees can range from $100 to $20,000 per port, per month. For example, BYX assesses a fee of $2,500 to $7,500 per month per FIX physical port (depending on the size of the port). For logical ports, BYX charges $550/port/month. *See https://www.cboe.com/us/equities/membership/fee_schedule/byx.* Nasdaq Stock Market LLC (''Nasdaq'') assesses fees for physical connections ranging from $2,500 to $20,000 (based on the size and type of physical connection). For Logical ports, Nasdaq charges $575/port/month. *See http://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2.* IEX does not charge for the first five ports (above 5 ports, IEX charges $100/port/month). *https://exchange.iex.io/resources/trading/get-connected-directly/index.html.*

[43] IntelligentCross does not assess other charges that may be assessed by exchanges, such as membership fees, trading rights fees, risk gateway fees and other miscellaneous fees. FINRA notes that these are the current fees assessed and rebates paid by IntelligentCross, and that IntelligentCross' fees may be subject to change. In the event that IntelligentCross makes a material change to the policies and procedures governing access to IntelligentCross, including a change to its fees, IntelligentCross has represented that it will submit the changes made to FINRA, and acknowledges that FINRA will post on its website an amended description of IntelligentCross' policies, procedures and fees governing access. Changes to the operations of IntelligentCross, as well as its disclosures on its public Form ATS–N, are subject to the requirements of Rule 304 of Regulation ATS.

[44] 15 U.S.C. 78*o*–3(b)(6).

[45] 15 U.S.C. 78*o*–3(b)(9).

[46] 15 U.S.C. 78*o*–3(b)(11).

be distributed or published by any member or person associated with a member, and the persons to whom such quotations may be supplied. Such rules relating to quotations must be designed to produce fair and informative quotations, to prevent fictitious or misleading quotations, and to promote orderly procedures for collecting, distributing, and publishing quotations.

FINRA believes the proposed rule change is consistent with the Act because it is being submitted pursuant to Rule 610 of Regulation NMS and the requirements set forth in the NMS Adopting Release, which require FINRA to submit a proposed rule change upon the addition of a new ADF participant. This proposed rule change is also consistent with the Act in that it sets forth the fees, policies and procedures governing access to protected quotations ASPEN Fee/Fee may display on the ADF, which were identified by the Commission as central concerns surrounding the adoption of Rule 610.

FINRA believes that IntelligentCross' policies, procedures and standards governing access to ASPEN Fee/Fee's quotations are consistent with the objectives of Regulation NMS and provide market participants with fair and efficient access and are not unfairly discriminatory. For example, as provided in IntelligentCross' summary, any registered U.S. broker-dealer can be a subscriber of ASPEN Fee/Fee and must be in good standing with an SRO to be eligible to become a subscriber, and subscribers also must satisfy certain other eligibility requirements.[47]

Both subscribers and non-subscribers may access liquidity on ASPEN Fee/Fee; when ASPEN Fee/Fee displays orders through the ADF, non-subscribers would access ASPEN Fee/Fee through a subscriber, and ASPEN Fee/Fee would therefore respond to orders by non-subscribers as promptly as it responds to orders by subscribers. IntelligentCross allows a subscriber to determine its level of connectivity,[48] and ASPEN Fee/Fee does not have any tiers or rules regarding execution of orders based upon the subscriber's identity. In addition, and as discussed above, IntelligentCross has represented that no subscriber (or non-subscribers accessing IntelligentCross through a subscriber) is given any type of priority through the ASPEN Fee/Fee matching process, the ASPEN Fee/Fee matching process is blind to the identity of the subscriber (or a non-subscriber accessing IntelligentCross through a subscriber), and the ASPEN Fee/Fee matching mechanism applies uniformly to all subscribers (and non-subscribers accessing the ASPEN Fee/Fee book through a subscriber). FINRA believes that the proposed level and cost of access is, in relative terms, substantially equivalent to the level and cost of access provided by SRO trading facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA notes that the purpose of this filing is to provide for the opportunity for public notice and comment on the addition of a new ADF entrant as required by Rule 610 of Regulation NMS and the NMS Adopting Release, along with that new entrant's proposed fees and policies and procedures for accessing protected quotations that it may display on the ADF. As such, FINRA believes that the proposed rule change may in fact promote competition by providing information about the level of access provided, and fees assessed, by a new ADF entrant.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

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 (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2022–032 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–FINRA–2022–032. 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 FINRA. 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–FINRA–2022–032, and should be submitted on or before January 17, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[49]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–28085 Filed 12–23–22; 8:45 am]

BILLING CODE 8011–01–P

[47] For example, a subscriber must pass Office of Foreign Asset Control checks and pass disciplinary/regulatory reviews. A subscriber also must satisfy such technical or systems requirements as may be prescribed by IntelligentCross. *See* IntelligentCross' Form ATS–N, Part III, Item 2.

[48] *See* IntelligentCross' Form ATS–N, Part III, Item 6.

[49] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96551; File No. SR–PEARL–2022–57]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by MIAX PEARL, LLC To Amend Exchange Rule 519C Mass Cancellation of Trading Interest

December 20, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 8, 2022, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the 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 is filing a proposal to amend Exchange Rule 519C.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/pearl* at MIAX Pearl's principal office, 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 Interpretations and Policies .01 of Exchange Rule 519C, Mass Cancellation of Trading Interest, to provide Members [3] the option of having the Exchange cancel all orders, including GTC Orders,[4] if the Exchange detects a loss of communication on a FIX Order Interface (''FOI'') Session.

MIAX PEARL Members may connect to the System using the MEO Interface [5] and/or the FIX Interface. These two connection protocols are not mutually exclusive and Members, specifically Market Makers (''MMs'') [6] on the Exchange, primarily use the MEO Interface for providing liquidity to the Exchange via their Market Making activities, while Electronic Exchange Members (''EEMs'') [7] primarily use the FIX Interface for submitting orders.[8]

These interface ports provide the mechanism by which Members maintain a connection to the Exchange and through which a Member communicates its quotes and/or orders to the System.[9] Market Makers may submit quotes [10] to the Exchange from one or more MEO ports. Similarly, Members may submit orders to the Exchange from one or more FIX ports.

FIX Connections

Members connect to their assigned FIX port using the MIAX PEARL FIX Orders Interface (''FOI'') which is a flexible interface that uses the FIX protocol for both application and session level messages. As per the FIX protocol, a connection is established by the Member submitting a logon message to the Exchange. This logon message establishes the Heartbeat interval that will be used by the session. The Exchange relies on heartbeat [11] messages to determine the status of the connection to ensure bi-directional communication remains intact. Upon missing a single heartbeat, FOI will send a *Test Request* message [12] to the Member to check the status of the connection. Upon missing a certain number of heartbeats,[13] FOI will send a logout message and terminate the connection. The Exchange currently offers Members certain order handling risk protection options in this scenario.

Specifically, when a Loss of Communication is detected on a FOI connection the System will logoff the Member's session and (i) cancel all eligible orders for the FIX Session if instructed by the Member upon login, or (ii) cancel all eligible orders identified by the Member. Following a disconnection, a reconnection will not be permitted for a certain period of time (''yy'' seconds). The Exchange shall determine the appropriate period of (''yy'' seconds) and shall notify Members of the value of ''yy'' seconds via Regulatory Circular. In no event shall ''yy'' be less than one (1) second or greater than ten (10) seconds.[14]

At the time the Exchange adopted this functionality the Exchange created an exception for Good 'Til Cancel Orders in Interpretations and Policies .01, which stated, Good 'Til Cancelled (''GTC'') orders, as defined in Rule 516 and PRIME Orders, as defined in Rule 515A, are not eligible for automatic cancellation under paragraph (c) of Rule 519C.[15]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] A Good 'til Cancelled or ''GTC'' Order is an order to buy or sell which remains in effect until it is either executed, cancelled or the underlying option expires. *See* Exchange Rule 516(i).

[5] The term ''MEO Interface'' means a binary order interface used for submitting certain order types (as set forth in MIAX PEARL Rule 516) to the MIAX Pearl System. *See* Exchange Rule 100.

[6] The term ''Market Maker'' or ''MM'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of MIAX Pearl Rules. *See* Exchange Rule 100.

[7] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[8] The term ''order'' means a firm commitment to buy or sell option contracts. *See* Exchange Rule 100.

[9] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[10] The term ''quote'' or ''quotation'' means a bid or offer entered by a Market Maker as a firm order that updates the Market Maker's previous bid or offer, if any. When the term order is used in these Rules and a bid or offer is entered by the Market Maker in the option series to which such Market Maker is registered, such order shall, as applicable, constitute a quote or quotation for purposes of these Rules. *See* Exchange Rule 100.

[11] A ''Heartbeat'' message is a communication which acts as a virtual pulse between the Exchange System and the Member's system. The Heartbeat message sent by the Member and received by the Exchange allows the Exchange to continually monitor its connection with the Member. *See* Interpretations and Policies .02(i) of Exchange Rule 519C.

[12] The test request message is a FIX Protocol message that forces a heartbeat from the opposing application. The test request message checks sequence numbers or verifies communication line status. The opposite application responds to the Test Request with a Heartbeat containing the Test Request ID. Financial Information Exchange Protocol (FIX), Version 4.2 with errata. May 1, 2001.

[13] The Exchange notes that the current System setting is two (2) heartbeats, and that any change to this setting will be determined by the Exchange and communicated to Members via Regulatory Circular.

[14] *See* Exchange Rule 519C(c)(2).

[15] *See* Interpretations and Policies .01 of Exchange Rule 519C.

Proposal

The Exchange now proposes to amend Interpretations and Policies .01 to allow GTC orders to also be eligible for cancellation when the Exchange detects a Loss of Communication.

As proposed, if the Exchange determines that there is a Loss of Communication, the Exchange will cancel the orders as described above, additionally, if elected, the Exchange proposes to cancel all GTC orders submitted through that FIX Session. As proposed, Members would need to contact the Exchange's Help Desk,[16] in a form and manner to be determined by the Exchange and communicated via Regulatory Circular, to have this optional order protection (cancellation of GTC orders) configured.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with section 6(b) of the Act [17] in general, and furthers the objectives of section 6(b)(5) of the Act [18] in particular, in that 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.

The disconnect feature of FIX connections is mandatory, however Members have the option to enable the cancellation of all orders for an entire session or select orders for cancellation on an order-by-order basis, which would result in the cancellation of orders submitted over a FIX Session when such session disconnects. The Exchange believes it is appropriate to offer an additional option for Members to have the Exchange cancel GTC orders from the order book when there is a communication issue between the Member and the Exchange, as a communication issue may or may not be quickly resolved.

Offering to cancel all orders (including GTC orders) allows the Member to customize Exchange risk protection functionality to align to a Member's business needs. Offering this type of order cancellation functionality to Members is consistent with the Act because it enables Members to have greater control over the execution of their orders in the event there is a communication issue with the Exchange. The proposed order cancellation functionality is designed to mitigate the risk of a missed execution associated with a loss of communication with the Exchange. The proposed rule change is not unfairly discriminatory among market participants, as it is available equally to all market participants utilizing a FOI connection to the Exchange.

The Exchange believes that the proposed rule change will assist with the maintenance of a fair and orderly market by providing Members with greater control over their resting orders. The Exchange's proposal is consistent with the Act because it will mitigate the risk of potential erroneous or unintended executions associated with a loss of communication which protects investors and the public interest. Additionally, the proposed rule adds another level of risk protection for Members and protects investors and the public interest by increasing the risk protection options available to Members of the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe that the proposed rule change to provide an additional risk protection imposes any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that adding an optional risk protection benefits all Members on the Exchange that use a FOI connection as any Member with a FOI connection can elect to use the risk protection described in the proposed rule.

The Exchange does not believe the proposed rule change will impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. For all the reasons stated, 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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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 after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [19] and Rule 19b–4(f)(6) [20] 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 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–PEARL–2022–57.

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–PEARL–2022–57. This file number should be included on the

[16] The term ''Help Desk'' means the Exchange's control room consisting of Exchange staff authorized to make certain trading determinations on behalf of the Exchange. The Help Desk shall report to and be supervised by a senior executive officer of the Exchange. *See* Exchange Rule 100.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change 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.

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–PEARL–2022–57, and should be submitted on or before January 17, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–28086 Filed 12–23–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96544; No. SR–NYSEARCA–2022–83]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

December 20, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 14, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule (''Fee Schedule'') regarding credits for Qualified Contingent Cross (''QCC'') transactions. The Exchange proposes to implement the fee change effective December 14, 2022.[4] The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to modify the credits offered for QCC transactions.[5] The Exchange proposes to implement the rule change on December 14, 2022.

Currently, the Exchange offers Floor Brokers a credit of ($0.22) per contract for Non-Customer vs. Non-Customer QCC transactions or ($0.11) per contract for Customer vs. Non-Customer QCC transactions.[6] The Exchange also currently offers an additional ($0.04) per contract credit to Floor Brokers on all Customer vs. Non-Customer QCC transactions if they execute at least 500,000 contracts of credit-eligible volume in QCC transactions in a month.[7] QCC executions in which a Customer is on both sides of the QCC trade are not eligible for a credit, and the maximum Floor Broker credit for QCC transactions is $375,000 per month per Floor Broker firm.[8]

The Exchange now proposes to offer the credits on QCC transactions currently available only to Floor Brokers to any broker submitting a QCC transaction to the Exchange (a ''Submitting Broker''), whether the broker is a Floor Broker on the Trading Floor or a broker that enters orders electronically through an interface with the Exchange. In other words, the Exchange proposes to offer the existing Floor Broker QCC credits to any OTP Holder or OTP Firm (collectively, ''OTP Holder'') that submits a QCC transaction to the Exchange.

The Exchange also proposes to increase the credit offered on Customer vs. Non-Customer QCC transactions from ($0.11) to ($0.16) and, in light of such proposed increase, to eliminate the additional ($0.04) credit currently offered on Customer vs. Non-Customer QCC transactions to Floor Brokers that execute at least 500,000 contracts of credit-eligible volume in QCC transactions in a month. The Exchange proposes to eliminate the additional credit currently offered to qualifying Floor Brokers because the proposed increased credit of ($0.16) on all Customer vs. Non-Customer QCC transactions would provide Submitting Brokers with a higher credit than the combination of the current ($0.11) and ($0.04) credits available on Customer vs. Non-Customer QCC transactions.

To effect these changes, the Exchange proposes to modify the Fee Schedule to substitute the term ''Submitting Broker'' for ''Floor Broker'' in connection with credits relating to QCC transactions.[9] First, the Exchange proposes to modify the Participant column of the table setting forth the fees and credits for QCC transactions to provide for a ''Submitting Broker credit for Non-

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed to amend the Fee Schedule on December 1, 2022 (SR–NYSEARCA–2022–79), then withdrew such filing and amended the Fee Schedule on December 14, 2022 (SR–NYSEARCA–2022–81), which latter filing the Exchange also withdrew on December 14, 2022.

[5] A QCC Order is defined as an originating order to buy or sell at least 1,000 contracts that is identified as being part of a qualified contingent trade coupled with a contra-side order or orders totaling an equal number of contracts. *See* Rule 6.62P–O(g)(1)(A).

[6] *See* Fee Schedule, QUALIFIED CONTINGENT CROSS (''QCC'') TRANSACTION FEES AND CREDITS, *available at: https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf.*

[7] *See id.* at Endnote 13.

[8] *See id.*

[9] *See* proposed Fee Schedule, QUALIFIED CONTINGENT CROSS (''QCC'') TRANSACTION FEES AND CREDITS & Endnote 13.

Customer vs. Non-Customer QCC Transaction'' and a ''Submitting Broker credit for Customer vs. Non-Customer QCC Transaction.'' The Exchange also proposes to modify Endnote 13 to refer to a ''Submitting Broker'' rather than a ''Floor Broker,'' such that Endnote 13 would provide that Customer vs. Customer QCC executions are not eligible for Submitting Broker credits on QCC executions and that the maximum QCC credit allowed will apply to a Submitting Broker firm. The Exchange also proposes to modify Endnote 13 to delete the sentence setting forth the additional ($0.04) credit on Customer vs. Non-Customer QCC transactions.

The Exchange also proposes conforming changes to modify the description of the Firm and Broker Dealer Monthly Fee Cap (the ''Monthly Fee Cap''), as well as Endnote 9, to eliminate text referring to QCC transactions executed by a Floor Broker from the Floor of the Exchange.[10] To reflect the proposed changes described above to extend the current Floor Broker QCC credits to any Submitting Broker (whether a Floor Broker on the Trading Floor or a broker that submits orders electronically), the Exchange proposes to delete references to the execution of QCC transactions by a Floor Broker on the on Floor of the Exchange. The Exchange does not propose any other modifications to the Monthly Fee Cap or Endnote 9.

Although the Exchange cannot predict with certainty whether the proposed change would encourage OTP Holders to increase their QCC volume, the proposed change is intended to incent OTP Holders to submit additional QCC transactions to the Exchange by expanding the universe of OTP Holders that would be eligible for credits on QCC transactions and increasing the amount of the credit offered on Customer vs. Non-Customer QCC transactions. The Exchange notes that the current Floor Broker QCC credits, when adopted, were offered to Floor Brokers based on their function in facilitating the execution of orders on the Exchange and intended to incent Floor Brokers to aggregate their trading activity, including QCC transactions, at the Exchange as a primary execution venue.[11] The instant proposal would continue to provide QCC credits to Floor Brokers and would offer QCC credits to other OTP Holders that submit QCC transactions to the Exchange as well. The Exchange believes the proposed change would continue to encourage Floor Broker QCC volume and also encourage additional OTP Holders to increase QCC volume submitted to the Exchange by offering credits on such transactions. The Exchange believes that the proposal, which also increases the credit on Customer vs. Non-Customer QCC transactions, could incentivize both Floor Brokers and other OTP Holders to aggregate their trading activity at the Exchange, thereby making the Exchange a more attractive venue for order execution and providing additional trading opportunities for all market participants.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[13] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[15] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in October 2022, the Exchange had less than 12% market share of executed volume of multiply-listed equity and ETF options trades.[16]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, modifications to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The Exchange believes that the proposed change is reasonable because it is designed to incent OTP Holders to increase the number of QCC transactions sent to the Exchange by offering credits to all OTP Holders that execute QCC transactions (*i.e.,* both continuing to offer credits to Floor Brokers and providing credits to brokers that submit QCC transactions electronically as well) and by increasing the amount of the credit offered on Customer vs. Non-Customer QCC transactions. To the extent that the proposed change attracts more volume to the Exchange from both Floor Brokers and brokers that submit orders electronically, this increased order flow would continue to make the Exchange a more competitive venue for order execution, which, in turn, promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system. The Exchange notes that all market participants stand to benefit from any increase in volume entered by Submitting Brokers, which could promote market depth, facilitate tighter spreads and enhance price discovery, to the extent the proposed change encourages OTP Holders to utilize the Exchange as a primary trading venue, and may lead to a corresponding increase in order flow from other market participants. In addition, any increased liquidity on the Exchange would result

[10] *See* proposed Fee Schedule, FIRM AND BROKER DEALER MONTHLY FEE CAP & Endnote 9.

[11] *See* Securities Exchange Act Release No. 95471 (August 11, 2022), 87 FR 50662 (August 17, 2022) (SR–NYSEARCA–2022–50) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[15] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[16] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.,* the Exchange's market share in equity-based options decreased from 12.30% for the month of October 2021 to 11.87% for the month of October 2022.

in enhanced market quality for all participants.

Finally, to the extent the proposed change continues to attract greater volume and liquidity, the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The Exchange's fees are constrained by intermarket competition, as OTP Holders may direct their order flow to any of the 16 options exchanges, including those offering rebates on QCC transactions.[17] Thus, OTP Holders have a choice of where they direct their order flow, including their QCC transactions. The proposed rule change is designed to continue to incent OTP Holders to direct liquidity and, in particular, QCC transactions to the Exchange. In addition, to the extent OTP Holders are incentivized to aggregate their trading activity at the Exchange, that increased liquidity could promote market depth, price discovery and improvement, and enhanced order execution opportunities for market participants.

The Exchange believes that the proposed conforming changes are reasonable because they would not modify the substantive provisions of the Monthly Fee Cap or Endnote 9, but would instead promote consistency and clarity in the Fee Schedule by removing text describing QCC transactions as executed by Floor Brokers on the Floor of the Exchange, consistent with the proposed changes described above to extend QCC credits to any Submitting Broker.

The Exchange cannot predict with certainty whether the proposed change would encourage OTP Holders to increase their QCC order flow to the Exchange, but believes that the proposed change, which would offer credits on QCC transactions to all Submitting Brokers and increase the amount of the credit available on Customer vs. Non-Customer QCC transactions, would incent OTP Holders to direct additional QCC transactions to the Exchange.

The Proposed Rule Change Is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposed QCC credits are based on the type of business transacted on the Exchange, and OTP Holders can attempt to submit QCC transactions to earn the credits or not. In addition, the proposed credits are equally available to all brokers that enter QCC transactions. The Exchange also believes that the proposed change is an equitable allocation of fees and credits because it would provide for QCC credits to all Submitting Brokers (including Floor Brokers, whose eligibility for QCC credits would not change) and a consistent credit amount for all Customer vs. Non-Customer QCC transactions. To the extent the proposed credits continue to incent Floor Brokers and encourage other brokers to direct increased liquidity to the Exchange, all market participants would benefit from enhanced opportunities for price improvement and order execution. The Exchange believes that the proposed conforming changes are equitable because they would promote consistency and clarity in the Fee Schedule by removing text describing QCC transactions as executed by Floor Brokers on the Floor of the Exchange, in support of the proposed change to extend QCC credits to any Submitting Broker, without modifying the existing substantive provisions of the Monthly Fee Cap or Endnote 9.

Moreover, the proposed credits are designed to incent Submitting Brokers to encourage OTP Holders to aggregate their executions—including QCC transactions—at the Exchange as a primary execution venue. To the extent that the proposed change achieves its purpose in attracting more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes the proposed change is not unfairly discriminatory because the proposed credits on QCC transactions would be available to all Submitting Brokers on an equal and non-discriminatory basis. The proposed change is also not unfairly discriminatory to Floor Brokers because, although the Exchange proposes to offer credits on QCC transactions to additional market participants, Floor Brokers would continue to be eligible for the QCC credits currently available to them. The Exchange also believes that the proposed conforming changes to the Monthly Fee Cap and Endnote 9 are not unfairly discriminatory because they are intended only to promote consistency and clarity in the Fee Schedule by removing text describing QCC transactions as executed by Floor Brokers on the Floor of the Exchange, in alignment with the proposed change to extend QCC credits to any Submitting Broker, and do not otherwise modify the substantive provisions of those sections.

The proposed credits are based on the type of business transacted on the Exchange, and OTP Holders are not obligated to execute QCC transactions. Rather, the proposal is designed to encourage OTP Holders to increase QCC volume sent to the Exchange and to utilize the Exchange as a primary trading venue for all transactions (if they have not done so previously). To the extent that the proposed change attracts more QCC transactions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

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.

[17] *See, e.g.,* EDGX Options Exchange Fee Schedule, QCC Initiator/Solicitation Rebate Tiers (applying ($0.14) per contract rebate up to 999,999 contracts for QCC transactions when only one side of the transaction is a non-customer or ($0.22) per contract rebate up to 999,999 contracts for QCC transactions with non-customers on both sides); BOX Options Fee Schedule at Section IV.D.1. (QCC Rebate) (providing for ($0.14) per contract rebate up to 1,499,999 contracts for QCC transactions when only one side of the QCC transaction is a broker-dealer or market maker or ($0.22) per contract rebate up to 1,499,999 contracts for QCC transactions when both parties are a broker-dealer or market maker); Nasdaq ISE, Options 7, Section 6.B. (QCC Rebate) (offering rebates on QCC transactions of ($0.14) per contract when only one side of the QCC transaction is a non-customer or ($0.22) per contract when both sides of the QCC transaction are non-customers).

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed 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.'' [18]

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange (particularly in QCC transactions), which could increase the volumes of contracts traded on the Exchange. Greater liquidity benefits all market participants on the Exchange, and increased QCC transactions could increase opportunities for execution of other trading interest. The proposed credit would be available to all similarly-situated Submitting Brokers that execute QCC trades. The Exchange does not believe that the proposed conforming changes would impose any burden on intramarket competition that is not necessary or appropriate, as they are intended only to promote clarity and consistency in the Fee Schedule in consideration of the proposed change to extend QCC credits to all Submitting Brokers, whether a Floor Broker or a broker that submits orders to the Exchange electronically.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[19] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in October 2022, the Exchange had less than 12% market share of executed volume of multiply-listed equity and ETF options trades.[20]

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees in a manner designed to continue to incent OTP Holders to direct trading interest (particularly QCC transactions) to the Exchange, to provide liquidity and to attract order flow. To the extent that Submitting Brokers are incentivized to utilize the Exchange as a primary trading venue for all transactions, all of the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement. The Exchange also believes that the proposed conforming changes would not impose any burden on intermarket competition that is not necessary or appropriate; the proposed conforming changes are intended only to promote consistency with the proposed change to extend QCC credits to all Submitting Brokers, whether a Floor Broker or a broker that submits orders to the Exchange electronically, thereby improving the clarity of the Fee Schedule.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment. The Exchange further believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer rebates on QCC transactions, by encouraging additional orders (and, in particular, QCC transactions) to be sent to the Exchange for execution.[21]

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) [22] of the Act and subparagraph (f)(2) of Rule 19b–4 [23] 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) [24] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2022–83 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–2022–83. This file number should be included on the subject line if email is used. To help the

[18] *See* Reg NMS Adopting Release, *supra* note 14, at 37499.

[19] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[20] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.*, the Exchange's market share in equity-based options decreased from 12.30% for the month of October 2021 to 11.87% for the month of October 2022.

[21] *See* note 17, *supra.*

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f)(2).

[24] 15 U.S.C. 78s(b)(2)(B).

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–2022–83, and should be submitted on or before January 17, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–28081 Filed 12–23–22; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17733; UTAH Disaster Number UT–00094 Declaration of Economic Injury]

Administrative Declaration of an Economic Injury Disaster for the State of Utah

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of UTAH dated 12/20/2022.

Incident: Severe Storm and Flooding.

Incident Period: 08/19/2022 through 08/21/2022.

DATES: Issued on 12/20/2022.

Economic Injury (EIDL) Loan Application Deadline Date: 09/20/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Grand.

Contiguous Counties:

Utah: Emery, San Juan, Uintah, Wayne

Colorado: Garfield, Mesa, Montrose

The Interest Rates are:

	Percent
Businesses and Small Agricultural Cooperatives without Credit Available Elsewhere	3.040
Non-Profit Organizations without Credit Available Elsewhere	1.875

The number assigned to this disaster for economic injury is 177330.

The States which received an EIDL Declaration #17733 are Colorado, Utah.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2022–28089 Filed 12–23–22; 8:45 am]

BILLING CODE 8026–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 670 (Sub-No. 2)]

Notice of Rail Energy Transportation Advisory Committee Vacancies

AGENCY: Surface Transportation Board.

ACTION: Notice of vacancies on Federal advisory committee and solicitation of nominations.

SUMMARY: The Surface Transportation Board (Board) hereby gives notice of nine vacancies on its Rail Energy Transportation Advisory Committee (RETAC) for three representatives from coal producers; one representative from electric utilities; one representative from biofuel feedstock growers or providers and biofuel refiners, processors, and distributors; one representative from private car owners, car lessors, or car manufacturers; two representatives from renewable energy sources; and one representative from a labor organization. The Board is soliciting nominations from the public for candidates to fill these vacancies.

DATES: Nominations for candidates for membership on RETAC are due January 26, 2023.

ADDRESSES: Nominations may be submitted either via the Board's e-filing format or in paper format. Any person using e-filing should attach a document and otherwise comply with the instructions at the E–FILING link on the Board's website, at *http://www.stb.gov.* Any person submitting a filing in paper format should send the original and 10 copies to: Surface Transportation Board, Attn: Docket No. EP 670 (Sub-No. 2), 395 E Street SW, Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Kristen Nunnally at 202–245–0312. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: The Board exercises broad authority over transportation by rail carriers, including rates and services (49 U.S.C. 10701–10747, 11101–11124), construction, acquisition, operation, and abandonment of railroad lines (49 U.S.C. 10901–10907), and consolidation, merger, or common control arrangements between railroads (49 U.S.C. 10902, 11323–11327).

The Board established RETAC in 2007 as a Federal advisory committee consisting of a balanced cross-section of energy and rail industry stakeholders to provide independent, candid policy advice to the Board and to foster open, effective communication among the affected interests on issues such as rail performance, capacity constraints, infrastructure planning and development, and effective coordination among suppliers, railroads, and users of energy resources. RETAC operates under the Federal Advisory Committee Act (5 U.S.C. app. 2, 1–16).

RETAC's membership is balanced and representative of interested and affected parties, consisting of not less than: five representatives from the Class I railroads; three representatives from Class II and III railroads; three representatives from coal producers; five representatives from electric utilities (including at least one rural

[25] 17 CFR 200.30–3(a)(12).

electric cooperative and one state- or municipally-owned utility); four representatives from biofuel feedstock growers or providers and biofuel refiners, processors, and distributors; two representatives from private car owners, car lessors, or car manufacturers; one representative from the petroleum shipping industry; two representatives from renewable energy sources; and one representative from a labor organization. The Committee may also include up to two at large members with relevant experience but not necessarily affiliated with one of the aforementioned industries or sectors.

Members are selected by the Chair of the Board with the concurrence of a majority of the Board. The Chair may invite representatives from the U.S. Departments of Agriculture, Energy, and Transportation and the Federal Energy Regulatory Commission to serve on RETAC in advisory capacities as *ex officio* (non-voting) members. The members of the Board serve as *ex officio* members of the Committee.

RETAC meets at least twice per year. Meetings are typically held at the Board's headquarters in Washington, DC, but may be held virtually or in other locations. Members of RETAC serve without compensation and without reimbursement of travel expenses. Further information about RETAC is available on the RETAC page of the Board's website at *http://www.stb.gov/stb/rail/retac.html.*

The Board is soliciting nominations from the public for candidates to fill nine vacancies: three representatives from coal producers; one representative from electric utilities; one representative from biofuel feedstock growers or providers and biofuel refiners, processors, and distributors; one representative from private car owners, car lessors, or car manufacturers; two representatives from renewable energy sources; and one representative from a labor organization. All the vacancies are for three-year terms ending September 30, 2026. According to revised guidance issued by the Office of Management and Budget, it is permissible for federally registered lobbyists to serve on advisory committees, such as RETAC, as long as they do so in a representative capacity, rather than an individual capacity. *See Revised Guidance on Appointment of Lobbyists to Fed. Advisory Comms., Bds., & Comm'ns,* 79 FR 47,482 (Aug. 13, 2014). Members of RETAC are appointed to serve in a representative capacity.

Nominations for candidates to fill the vacancies should be submitted in letter form and should include: (1) the name of the candidate; (2) the interest the candidate will represent; (3) a summary of the candidate's experience and qualifications for the position; (4) a representation that the candidate is willing to serve as a member of RETAC; and, (5) a statement that the candidate agrees to serve in a representative capacity. Candidates may nominate themselves. The Chair is committed to having a committee reflecting diverse communities and viewpoints and strongly encourages the nomination of candidates from diverse backgrounds. Nominations for candidates for membership on RETAC should be filed with the Board by January 26, 2023. Please note that submissions will be posted on the Board's website under Docket No. EP 670 (Sub-No. 2).

Authority: 49 U.S.C. 1321; 49 U.S.C. 11101; 49 U.S.C. 11121.

Decided: December 20, 2022.

By the Board, Cynthia T. Brown, Acting Director, Office of Proceedings.

Stefan Rice,

Clearance Clerk.

[FR Doc. 2022–28109 Filed 12–23–22; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 290 Sub–No. 5; 2023–1]

Quarterly Rail Cost Adjustment Factor; Decision

In *Railroad Cost Recovery Procedures,* 1 I.C.C.2d 207 (1984), the Interstate Commerce Commission (ICC) outlined the procedures for calculating the all-inclusive index of railroad input prices and the method for computing the rail cost adjustment factor (RCAF). Under the procedures, the Association of American Railroads (AAR) is required to calculate the index on a quarterly basis and submit it to the agency on the fifth day of the last month of each calendar quarter. In *Railroad Cost Recovery Procedures—Productivity Adjustment,* 5 I.C.C.2d 434 (1989), *aff'd sub nom. Edison Electric Institute* v. *ICC,* 969 F.2d 1221 (D.C. Cir. 1992), the ICC adopted procedures that require the adjustment of the quarterly index for a measure of productivity.

The provisions of 49 U.S.C. 10708 direct the Surface Transportation Board (Board) to continue to publish both an unadjusted RCAF and a productivity-adjusted RCAF. In *Productivity Adjustment—Implementation,* 1 S.T.B. 739 (1996), the Board decided to publish a second productivity-adjusted RCAF called the RCAF–5. Consequently, three indices are now filed with the Board: the RCAF (Unadjusted); the RCAF (Adjusted); and the RCAF–5. The RCAF (Unadjusted) is an index reflecting cost changes experienced by the railroad industry, without reference to changes in rail productivity. The RCAF (Adjusted) is an index that reflects national average productivity changes as originally developed and applied by the ICC, the calculation of which is currently based on a five-year moving average. The RCAF–5 is an index that also reflects national average productivity changes; however, those productivity changes are calculated as if a five-year moving average had been applied consistently from the productivity adjustment's inception in 1989.

As required by statute, the denominator of the RCAF is to be rebased every five years. *See* 49 U.S.C 10708(a). The Board has verified AAR's proposed rebasing calculations, and they comply with the statute. The rebasing calculations are shown in Table C of the Appendix.

The index of railroad input prices, RCAF (Unadjusted), RCAF (Adjusted), and RCAF–5 for the first quarter of 2023 are shown in Table A of the Appendix to this decision. Table B shows the third quarter 2022 index and the RCAF calculated on both an actual and a forecasted basis. The difference between the actual calculation and the forecasted calculation is the forecast error adjustment.

AAR's calculations have been examined by the Board's Office of Economics, and the Board finds that AAR has complied with agency procedures. The Board finds that the first quarter 2023 RCAF (Unadjusted) is 1.010, an increase of 1.0% from the fourth quarter 2022 RCAF (Unadjusted) of 1.000. The RCAF (Adjusted) is calculated, in part, using the RCAF (Unadjusted) and a five-year moving geometric average of productivity change for U.S. Class I railroads from 2016–2020, which is 1.025 (2.5% per year). The first quarter 2023 RCAF (Adjusted) is 0.408, an increase of 0.2% from the fourth quarter 2022 RCAF (Adjusted) of 0.407.[1]

In accordance with *Productivity Adjustment—Implementation,* 1 S.T.B. at 748–49, the RCAF–5 for this quarter will use a productivity trend for the years 2016–2020, which is 1.025 (2.5% per year). The RCAF–5 for the first quarter of 2023 is 0.390, an increase of

[1] The first quarter 2023 RCAF Adjusted (0.408) is calculated by dividing the first quarter 2023 RCAF Unadjusted (1.010) by the first quarter productivity adjustment factor (PAF) of 2.4740. The first quarter 2023 PAF is calculated by multiplying the fourth quarter 2022 productivity adjustment of 2.4588 by the fourth root (1.0062) of the 2016–2020 annual average productivity growth rate of 2.5%.

0.3% from the fourth quarter 2022 RCAF–5 of 0.389.[2]

This action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Authority: 49 U.S.C. 10708.

It is ordered:

1. The Board finds that the first quarter 2023 RCAF (Unadjusted) is 1.010, RCAF (Adjusted) is 0.408, and RCAF–5 is 0.390.

2. Notice of this decision will be published in the **Federal Register**.

3. The effective date of this decision is January 1, 2023.

Decided: December 20, 2022.

By the Board, Fuchs, Hedlund, Oberman, Primus, and Schultz.

Kenyatta Clay,

Clearance Clerk.

TABLE A—EP 290 (SUB–NO. 5) (2023–1) ALL INCLUSIVE INDEX OF RAILROAD INPUT COSTS

[Endnotes following Table C]

Line No.	Index component	2021 Weights (percent)	Fourth quarter 2022 forecast	First quarter 2023 forecast
1	LABOR	31.4	479.6	546.0
2	FUEL	14.2	475.2	467.1
3	MATERIALS AND SUPPLIES	4.5	335.3	328.9
4	EQUIPMENT RENTS	4.9	253.8	250.1
5	DEPRECIATION	17.5	233.3	234.8
6	INTEREST	2.4	50.1	50.1
7	OTHER ITEMS[1]	25.1	290.6	280.0
8	WEIGHTED AVERAGE	100.0	360.6	377.4
9	LINKED INDEX[2]		331.3	346.7
10	PRELIMINARY RAIL COST ADJUSTMENT FACTOR[3]		96.8	101.3
11	FORECAST ERROR ADJUSTMENT[4]		0.032	−0.003
12	RCAF (UNADJUSTED) (LINE 10 + LINE 11)		1.000	1.010
13	RCAF (ADJUSTED)		0.407	0.408
14	RCAF–5		0.389	0.390

TABLE B—EP 290 (SUB–NO. 5) (2023–1) COMPARISON OF THIRD QUARTER 2022 INDEX

[Calculated on both a forecasted and an actual basis]

Line No.	Index component	2020 Weights (%)	Third quarter 2022 forecast	Third quarter 2022 actual
1	LABOR	32.4	472.4	472.4
2	FUEL	9.7	459.6	484.4
3	MATERIALS AND SUPPLIES	4.5	305.0	305.0
4	EQUIPMENT RENTS	5.2	256.0	251.4
5	DEPRECIATION	18.5	233.2	233.7
6	INTEREST	2.7	51.1	51.1
7	OTHER ITEMS	27.0	302.4	289.7
8	WEIGHTED AVERAGE	100.0	350.8	349.7
9	LINKED INDEX		328.7	327.7
10	RAIL COST ADJUSTMENT FACTOR		96.0	95.7

TABLE C—REBASING THE DENOMINATOR OF THE RCAF TO THE FOURTH QUARTER 2022 LEVEL

1.	Fourth Quarter 2022 Linked Index	331.3
2.	Second Quarter 2022 Linked Index Calculated Using Actual Data	324.8
3.	Second Quarter 2022 Linked Index Calculated Using Forecasted Data	313.8
4.	Difference	11.0
5.	Rounding Adjustment to Force 1.000	0.0
6.	Fourth Quarter 2022 Linked Index Adjusted for Second Quarter 2022 Forecast Error (Line 1 plus Line 4 plus Line 5).	342.3

Endnotes:

[2] The first quarter 2023 RCAF–5 (0.390) is calculated by dividing the first quarter 2023 RCAF Unadjusted (1.010) by the first quarter productivity adjustment factor-5 (PAF–5) of 2.5898. The first quarter 2023 PAF–5 is calculated by multiplying the fourth quarter 2022 PAF–5 of 2.5738 by the fourth root (1.0062) of the 2016–2020 annual average productivity growth rate of 2.5%.

[1] "Other Items" is a combination of Purchased Services, Casualties and Insurance, General and Administrative, Other Taxes, Loss and Damage, and Special Charges, price changes for all of which are measured by the Producer Price Index for Industrial Commodities Less Fuel and Related Products and Power.

[2] Linking is necessitated by a change to the 2021 weights beginning in the fourth quarter of 2022. The following formula was used for the current quarter's index:

1st Qr. 2023 Index (2021 Weights) / 4th Qr. 2022 Index (2021 Weights)	Times	4th Quarter Linked Index (1980 = 100 Linked)	Equals Linked Index (Current Quarter)

Or

377.4 / 360.6 X 331.3 = 346.7

[3] The first quarter 2023 RCAF was rebased using the October 1, 2022 level of 342.3 in accordance with the requirements of the Staggers Rail Act of 1980 (10/1/2022 = 100). For the purpose of calculating the fourth quarter 2022 linked index (2022Q4 = 100), where the fourth quarter 2022 linked index equals 100 after the forecast error adjustment, the fourth quarter 2022 RCAF is also recalculated using the October 1, 2022 level of 342.3.

[4] The first quarter 2023 forecast error adjustment was calculated as follows: (a) third quarter 2022 RCAF using forecasted data equals 96.0; (b) third quarter 2022 RCAF using actual data equals 95.7; and (c) the difference equals the forecast error (b-a) of -0.3. Because the actual third quarter value is less than the forecast value, the difference is subtracted from the Preliminary RCAF.

[FR Doc. 2022–28110 Filed 12–23–22; 8:45 am]
BILLING CODE 4915–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Actions Taken at December 15, 2022 Meeting

AGENCY: Susquehanna River Basin Commission

ACTION: Notice.

SUMMARY: As part of its regular business meeting held on December 15, 2022, in Harrisburg, Pennsylvania, the Commission approved the applications of certain water resources projects, and took additional actions, as set forth in the Supplementary Information below.

DATES: December 15, 2022.

ADDRESSES: Susquehanna River Basin Commission, 4423 N Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary, telephone: (717) 238–0423, ext. 1312, fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address. See also Commission website at *www.srbc.net.*

SUPPLEMENTARY INFORMATION: In addition to the actions taken on projects identified in the summary above these actions were also taken: (1) adoption of the regulatory program fee schedule for CY2023; (2) adoption of a resolution recognizing the 50th anniversary of the Clean Water Act; (3) and approval of contracts, grants and agreements.

Project Applications Approved

1. *Project Sponsor and Facility:* Blossburg Municipal Authority, Bloss Township, Tioga County, Pa. Applications for groundwater withdrawals (30-day averages) of up to 0.144 mgd from Taylor Run Well 1 and 0.144 mgd from Taylor Run Well 3.

2. *Project Sponsor and Facility:* BlueTriton Brands, Inc. (Valley View Springs), Hegins Township, Schuylkill County, Pa. Applications for renewal of surface water withdrawal of up to 0.200 mgd (peak day) and consumptive use of up to 0.200 mgd (peak day) (Docket No. 19971101).

3. *Project Sponsor:* Constellation Energy Generation, LLC. Project Facility: Three Mile Island Generating Station, Londonderry Township, Dauphin County, Pa. Applications for renewal of groundwater withdrawals (30-day averages) of up to 0.099 mgd from Well A, 0.099 mgd from Well B, and 0.099 mgd from Well C (Docket No. 20110610), and Commission-initiated modification of surface water and consumptive use approvals based on changes in operating status of the project and revised demand projections.

4. *Project Sponsor:* Corning Incorporated. Project Facility: Corporate Headquarters, City of Corning, Steuben County, N.Y. Application for renewal of groundwater withdrawal of up to 1.440 mgd (30-day average) from Well 6A (Docket No. 19981201).

5. *Project Sponsor and Facility:* Dover Township, York County, Pa. Applications for groundwater withdrawals (30-day averages) of up to 0.088 mgd from Well 10 (Docket No. 19911104).

6. *Project Sponsor and Facility:* Hughesville Borough Authority, Wolf Township, Lycoming County, Pa. Applications for renewal of groundwater withdrawals (30-day averages) of up to 0.260 mgd from Well 1, 0.260 mgd from Well 2, and 1.440 mgd from Well 3 (Docket No. 20070604).

7. *Project Sponsor:* Municipal Authority of the Township of East Hempfield. Project Facility: Hempfield Water Authority, East Hempfield Township, Lancaster County, Pa. Applications for renewal of groundwater withdrawals (30-day averages) of up to 0.353 mgd from Well 6, 0.145 mgd from Well 7, 1.447 mgd from Well 8, and 1.800 mgd from Well 11, and Commission-initiated modification to Docket No. 20120906, which approves withdrawals from Wells 1, 2, 3, 4, and 5 and Spring S–1 (Docket Nos. 19870306, 19890503, 19930101, and 20120906).

8. *Project Sponsor and Facility:* Repsol Oil & Gas USA, LLC (Choconut Creek), Choconut Township, Susquehanna County, Pa. Application for renewal of surface water withdrawal of up to 0.999 mgd (peak day) (Docket No. 20171206).

9. *Project Sponsor:* State College Friends Limited Partnership. Project Facility: Toftrees Golf Resort (Pond 9), Patton Township, Centre County, Pa. Applications for surface water withdrawal of up to 0.750 mgd (peak day), and renewal with modification to increase consumptive use (peak day) by an additional 0.480 mgd, for a total consumptive use of up to 0.750 mgd (Docket No. 20021010).

10. *Project Sponsor and Facility:* SWN Production Company, LLC (Lycoming Creek), Lewis Township, Lycoming County, Pa. Application for renewal of surface water withdrawal of up to 0.500 mgd (peak day) (Docket No. 20171208).

11. *Project Sponsor and Facility:* SWN Production Company, LLC (Lycoming Creek), McIntyre Township, Lycoming County, Pa. Application for renewal of surface water withdrawal of up to 0.500 mgd (peak day) (Docket No. 20171209).

12. *Project Sponsor:* The United States Department of Veterans Affairs. Project Facility: Indiantown Gap National Cemetery, East Hanover and Union Townships, Lebanon County, Pa. Application for consumptive use of up to 0.099 mgd (30-day average).

13. *Project Sponsor:* Veolia Water Pennsylvania, Inc. Project Facility: Grantham Operation, Upper Allen Township, Cumberland County, Pa. Application for renewal of groundwater withdrawal of up to 0.395 mgd (30-day average) from Well 2 (Docket No. 19901104).

Project Scheduled for Action Involving a Diversion

1. *Project Sponsor and Facility:* BlueTriton Brands, Inc. (Valley View Springs), Hegins Township, Schuylkill County, Pa. Application for approval of an out-of-basin diversion of up to 0.200 mgd (peak day).

Project Tabled

1. *Project Sponsor and Facility:* Dover Township, York County, Pa. Applications for groundwater withdrawals (30-day averages) of up to 0.360 mgd from Well 8 (Docket No. 19911104).

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: December 20, 2022.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2022–28055 Filed 12–23–22; 8:45 am]

BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists Approvals by Rule for projects by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: November 1–30, 2022.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: *joyler@srbc.net.* Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22 (f) for the time period specified above:

Water Source Approval—Issued Under 18 CFR 806.22 f):

1. Chesapeake Appalachia, L.L.C. ; Pad ID: Keeler Hollow; ABR–201009041.R2; Smithfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 14, 2022.

2. EXCO Resources (PA), LLC; Pad ID: Fulmer Drilling Pad #1; ABR–20100616.R2; Franklin Township, Lycoming County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: November 14, 2022.

3. Repsol Oil & Gas USA, LLC; Pad ID: ABELL (05 112) G; ABR–201209002.R2; Warren Township, Bradford County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: November 14, 2022.

4. Seneca Resources Company, LLC; Pad ID: Bauer 849 2022; ABR–202211001; Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 14, 2022.

5. Chesapeake Appalachia, L.L.C.; Pad ID: Delhagen; ABR–201009066.R2; Rush Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 22, 2022.

6. Chesapeake Appalachia, L.L.C.; Pad ID: Driscoll; ABR–201009061.R2; Overton Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 22, 2022.

7. Coterra Energy Inc.; Pad ID: StockholmK P1; ABR–20100663.R2; Dimock Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: November 22, 2022.

8. Inflection Energy (PA) LLC; Pad ID: Fox B Well Site; ABR–201709001.R1; Shrewsbury Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 22, 2022.

9. Seneca Resources Company, LLC; Pad ID: Erickson 448; ABR–201009050.R2; Delmar Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 22, 2022.

10. Seneca Resources Company, LLC; Pad ID: Kalke 819; ABR–201009042.R2; Chatham Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 22, 2022.

11. Seneca Resources Company, LLC; Pad ID: Lingle 1102; ABR–201009049.R2; Deerfield Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 22, 2022.

12. Seneca Resources Company, LLC; Pad ID: Owlett 843; ABR–201009058.R2; Middlebury Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 22, 2022.

13. Chesapeake Appalachia, L.L.C.; Pad ID: Bennett NMPY–38; ABR–201009069.R2; Tuscarora Township,

Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 23, 2022.

14. EQT ARO LLC; Pad ID: COP Tr 731 Pad A; ABR–201009057.R2; Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 23, 2022.

15. Repsol Oil & Gas USA, LLC; Pad ID: Schmelzle 703; ABR–201009064.R2; Union Township, Tioga County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: Nov ember 23, 2022.

16. SWN Production Company, LLC; Pad ID: FREITAG PAD; ABR–201209010.R2; Jackson Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: November 23, 2022.

17. SWN Production Company, LLC; Pad ID: MARVIN PAD; ABR–201209009.R2; Jackson Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: November 23, 2022.

18. SWN Production Company, LLC; Pad ID: SWOPE PAD; ABR–201209007.R2; Jackson Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: November 23, 2022.

19. Chesapeake Appalachia, L.L.C.; Pad ID: Balent NEW; ABR–201008149.R2; Wysox Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 29, 2022.

20. Chesapeake Appalachia, L.L.C.; Pad ID: Donna; ABR–201008096.R2; Terry Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 29, 2022.

21. Chesapeake Appalachia, L.L.C.; Pad ID: Governale; ABR–201009082.R2; Wysox Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 29, 2022.

22. Chesapeake Appalachia, L.L.C.; Pad ID: Lambert Farms; ABR–201008011.R2; Forks Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 29, 2022.

23. Chesapeake Appalachia, L.L.C. ; Pad ID: Matt; ABR–201009073.R2; Elkland Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 29, 2022.

24. Chesapeake Appalachia, L.L.C.; Pad ID: Rain; ABR–201009077.R2; Elkland Township, Sullivan County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 29, 2022.

25. Chesapeake Appalachia, L.L.C.; Pad ID: Warren; ABR–201008010.R2; Windham Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 29, 2022.

26. Seneca Resources Company, LLC; Pad ID: Pichler 1H; ABR–201509003.R1; Jay Township, Elk County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: November 29, 2022.

27. SWN Production Company, LLC; Pad ID: WOOSMAN PAD; ABR–201209006.R2; New Milford Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: Nov ember 29, 2022.

28. Chesapeake Appalachia, L.L.C.; Pad ID: Boyanowski; ABR–201009076.R2; Meshoppen Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2022.

29. Chesapeake Appalachia, L.L.C.; Pad ID: Clarke; ABR–201008145.R2; Overton Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2022.

30. Chesapeake Appalachia, L.L.C.; Pad ID: Earnshaw; ABR–201508003.R1; Mehoopany Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2022.

31. Chesapeake Appalachia, L.L.C.; Pad ID: Foster; ABR–201009093.R2; Wysox Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2022.

32. Chesapeake Appalachia, L.L.C.; Pad ID: Hope; ABR–201009102.R2; Meshoppen Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2022.

33. Chesapeake Appalachia, L.L.C.; Pad ID: Scheffler; ABR–201007102.R2; Standing Stone Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2022.

34. Chesapeake Appalachia, L.L.C.; Pad ID: Van DeMark; ABR–201007106.R2; Windham Township, Wyoming County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: November 30, 2022.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806 and 808.

Dated: December 20, 2022.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2022–28056 Filed 12–23–22; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–1172]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: FAA Acquisition Management System (FAAAMS)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 1, 2022. The collection involves the FAA Acquisition Management System (FAAAMS) and information collected in response to solicitations and post award contract administration. The information to be collected is necessary to solicit, award, and administer contracts for supplies, equipment, services, facilities, and real property to fulfill the FAA's mission.

DATES: Written comments should be submitted by January 20, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Stephen Mangan by email at: *Stephen.mangan@faa.gov;* phone: 405–954–4137.

SUPPLEMENTARY INFORMATION: *Public Comments Invited:* You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0595.

Title: FAA Acquisition Management System (FAAAMS).

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 1, 2022 (87 FR 53283). No comments were received in response to this Notice. The FAAAMS establishes policies and internal procedures for FAA acquisition. Section 348 of Public Law 104–50 directed FAA to establish an acquisition system. The information collection is carried out as an integral part of FAA's acquisition process. Various portions of the AMS describe information needed from vendors seeking or already doing business with FAA. FAA contracting offices collect the information to plan, solicit, award, administer and close individual contracts. FAA's small business office collects information to promote and increase small business participation in FAA contracts. Activities for this information collection involve the reporting of information. Responses are voluntary in some cases, but in other cases are required to obtain a benefit (such as responses to Requests for Offers leading to award of a contract). These information collection practices aid in ensuring AMS compliance at large.

FAAAMS requires information collection through a series of forms in the areas of (1) Solicitations and (2) Post-Award Contract Administration. The specific information collected varies by the nature of each form. It is important to note the FAA uses forms specific to the agency. FAA uses forms similar to government wide standard forms. The FAA forms differ from standard forms as they are tailored or prescribed by FAAAMS. Though the forms differ, they do however largely mirror their counterpart standard forms while containing minor editorial changes to account for them being prescribed by the FAAAMS.

IC–1 Solicitations—The FAA utilizes solicitations to evaluate vendor-specific technical solutions, capabilities, and other qualifications such as subcontracting plans that may result in the award of a contract for a defined FAA need. The extent and nature of the information required from vendors varies depending on the nature of the goods and/or services procured, as well as the size and complexity of the FAA requirements.

Respondents: Contractors with an interest in or involved with FAA Acquisitions: 3,461.

Frequency: 1 time.

Estimated Average Burden per Response: 3 hours.

Estimated Total Annual Burden: 10,383 hours.

IC–2 Post-Award Contract Administration—Depending on the complexity and size of the contract, various activities are ongoing after contract award in areas such as bonds (*e.g.*, construction contracts), small business subcontracting (*e.g.* applying to large businesses), the tracking and management of Government Property, and invoicing. Contract modifications vary from routine administrative updates to major additions of work.

Respondents: Contractors with an interest in or involved with FAA Acquisitions: 30,177.

Frequency: 3 times.

Estimated Average Burden per Response: 23 hours.

Estimated Total Annual Burden: 702,213 hours.

Issued in Washington, DC, on December 20, 2022.

Michelle G. Brune,

Division Manager, Acquisition Policy Division (AAP–100).

[FR Doc. 2022–28102 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0107]

Agency Information Collection Activities; Renewal of an Approved Information Collection: Designation of Agents, Motor Carriers, Brokers and Freight Forwarders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. FMCSA requests approval to renew an ICR titled ''Designation of Agents, Motor Carriers, Brokers and Freight Forwarders,'' OMB control number 2126–0015. This is necessary to provide motor carriers, property brokers, and freight forwarders a means of meeting process agent requirements. No comments were received from the 60-day **Federal Register** publication.

DATES: Comments on this notice must be received on or before January 26, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Lorenzo Allen, Office of Registration, DOT, FMCSA, 6th Floor, West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; 202–385–2465; *lorenzo.allen@dot.gov.*

SUPPLEMENTARY INFORMATION: *Title:* Designation of Agents, Motor Carriers, Brokers and Freight Forwarders.

OMB Control Number: 2126–0015.

Type of Request: Renewal.

Respondents: Motor carriers, freight forwarders and brokers.

Estimated Number of Respondents: 20,649.

Estimated Time per Response: 10 minutes, or 0.167 hours.

Expiration Date: January 31, 2023.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 3,448 hours (20,649 respondents × 0.167 hours per response).

Background

The Secretary of Transportation (Secretary) is authorized to register motor carriers under the provisions of 49 U.S.C. 13902; freight forwarders under the provisions of 49 U.S.C. 13903; and property brokers under provisions of 49 U.S.C. 13904. These persons may conduct transportation services only if they are registered pursuant to 49 U.S.C. 13901. The Secretary delegated authority pertaining to these registration requirements to FMCSA in 49 CFR 1.73(a)(5).

Registered motor carriers, brokers, and freight forwarders must designate an agent on whom service of notices in proceedings before the Secretary may be made (49 U.S.C. 13303). Registered motor carriers must also designate an agent for every State in which they operate and traverse in the United States during such operations, on whom process issued by a court may be served in actions brought against the registered motor carrier (49 U.S.C. 13304, 49 CFR 366.4T). Every broker shall make a designation for each State in which its offices are located or in which contracts are written (49 U.S.C. 13304, 49 CFR 366.4T). Regulations governing the designation of process agents are found at 49 CFR part 366. This designation is filed with FMCSA on Form BOC–3, ''Designation of Agents for Service of Process.''

For this renewal, the program's annual burden hours decreased from 6,508 to 3,448. This is due to an updated estimate of the number of respondents and responses.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,

Associate Administrator, Office of Research and Registration.

[FR Doc. 2022–28042 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0235]

Agency Information Collection Activities; New Information Collection: Crash Causal Factors Program: Knowledge of Systems and Processes

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. This ICR relates to the planned ''Study of Commercial Motor Vehicle Crash Causation,'' mandated by Congress in the Infrastructure and Investment Jobs Act (IIJA). To plan and execute this study, FMCSA must collect information from the States and local jurisdictions to understand their interest or ability to participate in the study; existing crash data collection processes, systems, and resources; and commercial motor vehicle (CMV) enforcement funding mechanisms and sources.

DATES: Comments on this notice must be received on or before February 27, 2023.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Docket Number FMCSA–2022–0235 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC, 20590–0001 between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments, see the Public Participation heading below. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov,* and follow the online instructions for accessing the docket, or go to the street address listed above.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Public Participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the ''FAQ'' section of the Federal eRulemaking Portal website. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket and will be considered to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Kelly Stowe, Office of Analysis, Research, and Technology/Research Division, DOT, FMCSA, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; 617–386–6807; *kelly.stowe@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background: On December 27, 2020, the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), was signed into law, appropriating $30 million to FMCSA to ''carry out [a] study of the cause[s] of large truck crashes.'' On November 14, 2021, the President signed into law the IIJA (Pub. L. 117–58), which contains requirements for a larger study under section 23006, ''Study of Commercial Motor Vehicle Crash Causation.'' The requirements under section 23006 define the scope of the study to include all CMVs as defined in 49 U.S.C. 31132.

Section 23006(b)(1) of the IIJA requires the Secretary to ''carry out a comprehensive study to determine the causes of, and contributing factors to, crashes that involve a commercial motor vehicle.'' Section 23006(b)(2) further requires the Secretary to:

A. Identify data requirements, data collection procedures, reports, and any other measures that can be used to improve the ability of States and the Secretary to evaluate future crashes involving commercial motor vehicles;

B. Monitor crash trends and identify causes and contributing factors; and

C. Develop effective safety improvement policies and programs.

To meet the requirements of section 23006, FMCSA is establishing a Crash Causal Factors Program. Through this program, FMCSA will execute a multi-phased study of crash causal factors, with Phase 1 focused on fatal crashes involving Class 7/8 large trucks. This Phase 1 effort is referred to as the Large Truck Crash Causal Factors Study. Future phases of the study will focus on different CMV populations (such as medium-duty trucks) or crash severities (*e.g.,* serious injury crashes).

Congress anticipated that FMCSA would need to consult with the States and a variety of other experts when planning and executing the study, as noted in section 23006(d), which reads: ''In designing and carrying out the study, the Secretary may consult with individuals or entities with expertise on—

1. Crash causation and prevention;

2. Commercial motor vehicles, commercial drivers, and motor carriers, including passenger carriers;

3. Highways and noncommercial motor vehicles and drivers;

4. Federal and State highway and motor carrier safety programs;

5. Research methods and statistical analysis; and

6. Other relevant topics, as determined by the Secretary.''

This information collection (IC) will collect data from Federal, State, and

local highway and motor carrier safety programs. It will focus on identifying and documenting States' and local jurisdictions' interest in participating in the study; agreements that the States or jurisdictions will require to participate in the study; existing crash data collection processes, systems, tools, training, and quality control processes; and CMV enforcement funding mechanisms and sources.

How the Agency Will Use Collected Information

FMCSA will use collected information from four ICs:

- *IC–1:* Identifying Points of Contact
- *IC–2:* Sample Design; Partnerships and Coordination
- *IC–3:* Crash Data Collection
- *IC–4:* CMV Enforcement Resources and Funding

Information collected under these four ICs will inform various elements of the study plan, including the sample design, data collection plans, participation agreements, resourcing plans, and development of the study database. Below are additional details on how FMCSA will use collected information to develop various study plan elements.

IC–1: Identifying Points of Contact

Before collecting information for ICs 2, 3, and 4, FMCSA will first need to identify the appropriate points of contact in each State/jurisdiction for the remaining IC components. Once FMCSA obtains contact information from the States, the Agency will distribute a web-based survey for IC–2, IC–3, and IC–4 to the relevant point of contact in each State or jurisdiction. Below are additional details on how FMCSA will use collected information to develop various study plan elements.

IC–2: Sample Design; Partnerships and Coordination

The original Large Truck Crash Causation Study conducted from 2001 through 2003 leveraged the sample design from the National Highway Traffic Safety Administration's (NHTSA) National Automotive Sampling System (NASS) Crashworthiness Data System (CDS). NHTSA has since developed a new Crash Investigation Sampling System (CISS), which replaces NASS CDS. Both NASS CDS and CISS are focused on crashes involving passenger vehicles (*i.e.,* passenger cars, light trucks, vans, and utility vehicles). Neither sampling system was designed to collect data on a representative sample of crashes involving CMVs. NHTSA acknowledged this in its 2019 sample design and weighting documentation for CISS, stating in a discussion on special crash populations, ''The most efficient way to study a rare population is to design a special study that solely targets that particular rare population.'' As a result, FMCSA is planning to develop a new sample design specific to crashes involving CMVs. However, FMCSA cannot simply select a random sample of State and local jurisdictions to include in the sample design. The Agency will need to identify an appropriate mix of State and local jurisdictions to allow for a nationally representative sample design. Participating States and local jurisdictions will be asked to collect and share the required study data and troubleshoot study-related issues as they arise. The information collected under IC–2 will inform the sample design for this study. It will also provide important information about State- or local jurisdiction-required participation and data sharing agreements.

IC–3: Crash Data Collection

FMCSA is planning to leverage existing State and local jurisdiction resources (where possible) to collect required study data. This will be a complex effort that will require substantial information sharing and coordination between participating States/jurisdictions and FMCSA.

Under IC–3, FMCSA will seek to learn more about the data elements that State and local jurisdictions are already collecting; State and local jurisdiction CMV crash reporting criteria and notification systems; State and local jurisdiction crash data collection systems and processes (*e.g.,* what systems exist, who owns the system(s), the data flow from roadside to the system, whether the system can interface with other systems, etc.); existing crash data collection trainings offered by the State/jurisdiction; existing State/jurisdiction crash data collection tools; and crash data quality reviews that States and local jurisdictions currently conduct. The Agency will use this information to inform the study crash data collection plan and requirements for the study database.

IC–4: CMV Enforcement Resources and Funding

FMCSA must collect information from States and local jurisdictions to understand whether existing commercial vehicle enforcement resources can meet the study needs, and if not, to determine how much additional funding or resources jurisdictions will require to collect the necessary data. IC–4 will identify available CMV enforcement resources within States/jurisdictions, funding sources for existing commercial vehicle enforcement resources and activities (*e.g.,* State-funded versus FMCSA grant-funded), and whether there is a mechanism for the local jurisdiction to receive study funding through FMCSA's grant programs (*i.e.,* as a sub-grantee). Information collected under IC–4 will also inform FMCSA resourcing plans outside of the States/jurisdictions (*e.g.,* whether the Agency will need to hire third-party interviewers to interview involved drivers, motor carriers, and witnesses).

Method of Collection

FMCSA will collect the required information for IC–1 via email. For ICs 2, 3, and 4, FMCSA will leverage a web-based survey application combined with a document sharing platform (*e.g.,* SharePoint, Huddle) or email (if needed) to collect information. FMCSA believes that all respondents will have State or local government-provided information technology equipment (*e.g.,* laptops, mobile devices, etc.) and internet access; as such, the Agency believes electronic submissions will be most cost-effective and efficient for respondents (as opposed to mail-based submissions or some other means). FMCSA estimates that 100 percent of submissions will be electronic.

Results of Data Collection

FMCSA does not plan to publish results from this data collection. Results from this data collection, which will be descriptive and/or qualitative in nature, will inform the study sample design, participation agreements, data collection plans, resource plans, and study database requirements. No complex analytical techniques will be used. Final results from the overall study, once completed, will be published in a final study report. Findings from the overall study will ultimately inform the identification and development of countermeasures to prevent crashes involving CMVs.

As part of the Crash Causal Factors Program, this information collection supports the DOT Strategic Goal of Safety.

Title: Crash Causal Factors Program: Knowledge of Systems and Processes.

OMB Control Number: 2126–00XX.

Type of Request: New ICR.

Respondents: State and local Government employees (first-line supervisors of police and detectives; police and sheriff's patrol officers; general and operations managers; chief executives; computer and information

systems managers; and computer and mathematical operations workers).

Estimated Number of Respondents: 2,160 respondents.

Estimated Time per Response: 2 hours per response for IC–1, 2.5 hours per response for IC–2, 3.83 hours per response for IC–3, 1.67 hours per response for IC–4.

Expiration Date: N/A. This is a new ICR.

Frequency of Response: Once for IC–1 and IC–2; no more than once annually for IC–3 and IC–4.

Estimated Total Annual Burden: 9,127.5 hours total, or 3,042.5 hours annually (215.5 annual hours for State computer and information systems managers + 495 annual hours for local computer and information systems managers + 293.5 annual hours for State police and sheriff's patrol officers + 210 annual hours for local police and sheriff's patrol officers + 112 annual hours for State first-line supervisors of police and detectives + 705 annual hours for local first-line supervisors of police and detectives + 42.5 annual hours for State general and operations managers + 125 annual hours for local general and operations managers + 42.5 annual hours for State chief executives + 125 annual hours for local chief executives + 181.5 annual hours for State computer and mathematical operations workers + 495 annual hours for local computer and mathematical operations workers = 3,042.5 annual hours).

Definitions: N/A.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The Agency will summarize or include your comments in the request for OMB's clearance of this ICR.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,

Associate Administrator, Office of Research and Registration.

[FR Doc. 2022–28045 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Funding Opportunity for Projects Located on the Northeast Corridor for the Federal-State Partnership for Intercity Passenger Rail Program

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of funding opportunity (NOFO or Notice).

SUMMARY: This notice details the application requirements and procedures to obtain grant funding for projects located on the Northeast Corridor (NEC) under the Federal-State Partnership for Intercity Passenger Rail Program (FSP Program) for Fiscal Year 2022 and 2023. This notice solicits applications for FSP Program funds made available by the Consolidated Appropriations Act, 2022, and Division J of the Infrastructure Investment and Jobs Act (IIJA). The opportunity described in this notice is made available under Assistance Listings Number 20.326, ''Federal-State Partnership for Intercity Passenger Rail.''

DATES: Applications for funding under this solicitation are due no later than 5 p.m. ET, March 27, 2023. Applications that are incomplete or received after 5 p.m. ET, on March 27, 2023 will not be considered for funding. See *Section D* of this notice for additional information on the application process.

ADDRESSES: Applications must be submitted via *www.Grants.gov.* Only applicants who comply with all submission requirements described in this notice and submit applications through *www.Grants.gov* will be eligible for award. For any supporting application materials that an applicant is unable to submit via *www.Grants.gov* (such as oversized engineering drawings), an applicant may submit an original and two (2) copies to Mr. Bryan Rodda, Office of Amtrak and Northeast Corridor Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–203, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, applicants are advised to use other means of conveyance (such as courier service) to assure timely receipt of materials before the application deadline.

FOR FURTHER INFORMATION CONTACT: For further information related to this notice, please contact the FRA NOFO Support program staff via *FRA-NOFO-Support@dot.gov.* If additional assistance is needed, you may contact Mr. Bryan Rodda, Office of Amtrak and Northeast Corridor Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–203, Washington, DC 20590; email: *Bryan.Rodda@dot.gov;* telephone: 202–493–0443.

SUPPLEMENTARY INFORMATION: Notice to applicants: FRA recommends that applicants read this notice in its entirety prior to preparing application materials. Definitions of key terms used throughout the NOFO are provided in Section A(2) below. These key terms are capitalized throughout the NOFO. There are several administrative and specific eligibility requirements described herein with which applicants must comply. Additionally, applicants should note that the required Project Narrative component of the application package may not exceed 25 pages in length.

Table of Contents:

A. Program Description

1. Overview

The IIJA provided distinct FSP program selection criteria for projects located on the Northeast Corridor (NEC) and for projects not located on the NEC. For projects located on the NEC, the law requires projects to be selected for FSP program funds consistent with the Northeast Corridor Project Inventory (NEC Project Inventory). FRA published the NEC Project Inventory on November 15, 2022; the NEC Project Inventory can be found at *https://railroads.dot.gov/elibrary/nec-inventory.* This Notice solicits applications for the Major Backlog, Capital Renewal, Improvement, and Stations projects and Planning Studies identified on the NEC Project Inventory; it describes available FSP Program funding, application submission requirements, and the selection and evaluation criteria (FSP–NEC NOFO). For projects located off the NEC, FRA has published a separate notice on December 7, 2022, and those projects are not eligible for funding under this announcement. Under this Notice, FRA will make selections consistent with the NEC Project Inventory and only projects on the NEC

Project Inventory for which an application is submitted under this NOFO will be considered for award.

Our nation's rail network is a critical component of the U.S. transportation system and economy. The FSP Program provides a Federal funding opportunity to improve American intercity passenger rail infrastructure by funding projects that reduce the state of good repair backlog, improve performance, or expand or establish new intercity passenger rail service, including privately operated intercity passenger rail service if an eligible applicant is involved. Consistent with the NEC Project Inventory, FRA's first priority will be selecting Major Backlog projects and Planning Studies. FRA's second priority will be selecting other projects in or beginning the Final Design or Construction Lifecycle Stages within the Inventory Period.

The FSP Program is authorized in sections 22106 and 22307 of the IIJA, codified at 49 U.S.C. 24911, and this NOFO is funded by IIJA supplemental appropriations as provided in Title VIII of Division J of IIJA (Supplemental Appropriations), and the Consolidated Appropriations Act, 2022 (Pub. L. 117–103) (Appropriations Act). The opportunity described in this notice is made available under Assistance Listings Number 20.326, ''Federal-State Partnership for Intercity Passenger Rail.''

Discretionary grant awards, funded through the FSP–NEC NOFO, will support projects that improve safety, economic strength and global competitiveness, equity, climate and sustainability, and transformation, consistent with the U.S. Department of Transportation's (DOT) strategic goals.[1] Section E of this NOFO, which outlines the grant selection criteria, describes the process for selecting projects that further these goals. Section F of this NOFO provides further details on the Administration and National Policy Requirements to meet these goals and describes progress and performance reporting requirements for selected projects.

2. Definitions of Key Terms

Terms defined in this section are capitalized throughout this notice. Some definitions have been updated from those published in the NEC Project Inventory.

a. ''Capital Cost Estimate'' means an estimate of the cost to implement the Capital Project inclusive of Project Development through completion of Construction that accounts for risk to the cost elements and the schedule to complete the project.

b. ''Capital Project'' means a project for acquiring, constructing, improving or inspecting rail equipment, track and track structures, or a rail facility, including expenses incidental to the acquisition or construction including pre-construction activities (such as designing, engineering, location surveying, mapping, acquiring rights-of-way) and related relocation costs, environmental studies and all work necessary for FRA to approve the project under the National Environmental Policy Act; highway-rail grade crossing improvements; communication and signalization improvements; and rehabilitating, remanufacturing or overhauling rail rolling stock and rail facilities.

c. ''Commuter Rail Passenger Transportation'' means short-haul rail passenger transportation in metropolitan and suburban areas usually having reduced fare, multiple rides, and commuter tickets and morning and evening peak period operations, consistent with 49 U.S.C. 24102(3); the term does not include rapid transit operations in an urban area that are not connected to the general railroad system of transportation.

d. ''Construction'' means the Lifecycle Stage of a Capital Project when physical production of fixed works and structures, or substantial alterations to such structures or land, or production of vehicles and equipment are accomplished and commissioned for operational use. Construction includes associated project administration, test of equipment as appropriate, systems integration testing, workforce training, system certification, procurement of insurance, pre-revenue service, start-up testing, and other related costs.

e. ''Final Design (FD)'' means the Capital Project Lifecycle Stage when final design and engineering plans and specifications necessary for the Construction stage is completed, and at a minimum, includes (1) the preparation of final design plans consistent with the applicable environmental decision document, and detailed specifications, (2) the preparation of an updated Project Management Plan, (3) preparation of an updated project schedule, Capital Cost Estimate, and other necessary plans that may include a financial plan for Major Capital Projects, sufficiently detailed to inform decision makers of the actions required to advance the project through completion of Final Design and Construction. FD may include early construction or relocations and procure equipment and materials during the final design stage, when such work is permissible under applicable law, and may be combined with Construction with the use of alternative delivery methods.

f. ''Improvement'' means repair or enhancement to existing rail infrastructure, equipment, or facility, or construction of new rail infrastructure, equipment or facilities, that results in efficiency of the rail system and the safety of those affected by the system.

g. ''Inventory Period'' means the two-year period starting on the date the applicable Northeast Corridor Project Inventory was published.

h. ''Intercity Rail Passenger Transportation'' means rail passenger transportation, except commuter rail passenger transportation. See 49 U.S.C. 24911(a)(3). In this notice, ''Intercity Passenger Rail Service'' and ''Intercity Passenger Rail Transportation'' are equivalent terms to ''Intercity Rail Passenger Transportation.''

i. ''Lifecycle Stage'' means each of the consecutive stages of a Capital Project as it is developed and implemented that include Systems Planning, Project Planning, Project Development, Final Design, Construction, and Operation. Each sequential stage involves specific activities. FRA evaluates project readiness for a Lifecycle Stage when considering a project for funding.

j. ''Major Capital Project'' means a Capital Project with a Capital Cost Estimate of $500 million and with at least $100 million in federal assistance under the FSP Program.

k. ''National Environmental Policy Act'' (NEPA) is a federal law that requires Federal agencies to analyze and document the environmental impacts of a proposed action in consultation with appropriate Federal, state, and local authorities, and with the public. NEPA classes of action include an Environmental Impact Statement (EIS), Environmental Analysis (EA) or Categorical Exclusion (CE). The NEPA class of action depends on the nature of the proposed action, its complexity, and the potential impacts. For purposes of this NOFO, NEPA also includes all related Federal laws and regulations including the Clean Air Act, Section 4(f) of the Department of Transportation Act, Section 7 of the Endangered Species Act, and Section 106 of the National Historic Preservation Act. Additional information regarding FRA's environmental processes and requirements are located at *https://railroads.dot.gov/rail-network-development/environment/environment.*

[1] DOT Strategic Plan FY 2022–2026 (March 2022) at *https://www.transportation.gov/sites/dot.gov/files/2022-04/US_DOT_FY2022-26_Strategic_Plan.pdf.*

l. ''Northeast Corridor'' (''NEC'') means the main rail line between Boston, Massachusetts, and the District of Columbia; the branch rail lines connecting to Harrisburg, Pennsylvania, Springfield, Massachusetts, and Spuyten Duyvil, New York; and facilities and services used to operate and maintain these lines, consistent with 49 U.S.C. 24911(a)(3).

m. ''NEC Planning Documents'' means the Northeast Corridor Commission's CONNECT NEC 2035 and the FY 2023–2027 Northeast Corridor Capital Improvement Plan.

n. ''Planning Studies'' are those projects which include only planning activities such as railroad transportation market forecasting, operations analysis, fleet planning, cost analysis, station and facility planning, environmental resource consideration, and other similar activities. Planning Studies are planning activities without association to construction of a specific Capital Project in their current form.

o. ''Project Development'' means the Capital Project Lifecycle Stage during which (1) the environmental review process required under NEPA and other related environmental laws is completed, and the permitting processes is advanced as appropriate; (2) preliminary engineering and other preliminary design is completed to support the environmental review and preparation of estimates of risk, costs, benefits and impacts; (3) a Project Management Plan is prepared that, among other things, identifies procurement requirements and strategies; (4) preparation of the detailed project schedule and cost estimate; and (5) preparation of a financial plan for Major Projects and other necessary plans.

p. ''Project Planning'' means the Capital Project Lifecycle Stage during which the Project Sponsor (1) identifies capital project concepts to address transportation needs and opportunities; (2) identifies and compares costs, benefits and impacts of project options; and (3) identifies the impacted environmental resources and engages with interested parties, agencies and infrastructure owners.

q. ''Project Management Plan'' means a document, prepared in accordance with guidance, that describes how the Capital Project will be implemented, monitored, and controlled to help the applicant effectively, efficiently, and safely deliver the project on-time, within-budget, and at the highest appropriate quality.

r. ''Preliminary Engineering (PE)'' means engineering design to define a Capital Project, including identification of all environmental impacts and design of all critical project elements at a level sufficient to assure reliable cost estimates and schedules. The PE development process starts with specific project design alternatives that allow for the assessment of a range of rail improvements, specific alignments, and project designs.

s. ''Risk Assessment'' means the Major Capital Project cost and schedule risk assessment is an unbiased, risk-based, probabilistic analysis that verifies the accuracy and reasonableness of the current cost estimate and schedule and results in a probability range that represents the project's cost. It also documents how the estimate accounts for the range of potential costs associated with project uncertainties.

t. ''State of Good Repair'' means a condition in which physical assets, both individually and as a system, are (A) performing at a level at least equal to that called for in their as-built or as-modified design specification during any period when the life cycle cost of maintaining the assets is lower than the cost of replacing them; and (B) sustained through regular maintenance and replacement programs, consistent with 49 U.S.C. 24102(12).

B. Federal Award Information

1. Available Award Amount

The total funding available for awards under this NOFO is up to $8,979,150,000 made available by Supplemental Appropriations and the Appropriations Act, as follows:

a. Up to $8,928,000,000 in Supplemental Appropriations: IIJA provided $36,000,000,000 in Supplemental Appropriations for the FSP Program, with not more than $24,000,000,000 made available for projects for the NEC ($4,800,000,000 made available per year for fiscal years 2022 through 2026). After the funding set aside for FRA award and project management oversight and the planning and development activities authorized at 49 U.S.C. 24911(k), up to $8,928,000,000 in funding made available for fiscal years 2022 and 2023 is available for FSP awards under this NOFO.

b. Up to $51,150,000 in fiscal year 2022 annual appropriations: The Appropriations Act provided $100,000,000 for the FSP Program. Consistent with 49 U.S.C. 24911(d)(3), a minimum of 45 percent and a maximum of 55 percent of this amount is for projects for the NEC. After the funding set aside for FRA award and project management oversight and the planning and development activities authorized at 49 U.S.C. 24911(k), at least $41,850,000 and up to $51,150,000 in fiscal year 2022 annual funding is made available for FSP awards under this NOFO.

Should additional funds become available after the release of this FSP–NEC NOFO, FRA may elect to award such additional funds to applications received under this NOFO. Any selection and award under this NOFO is subject to the availability of appropriated funds.

2. Award Size

There are no predetermined minimum or maximum dollar thresholds for awards. FRA intends to make selections consistent with the NEC Project Inventory, subject to the application and evaluation process. FRA anticipates making multiple awards with the available funding. FRA may not be able to award grants to all eligible applications even if they meet or exceed the stated evaluation criteria (see Section E, Application Review Information). Projects may require more funding than is available. FRA encourages applicants to propose a project that has operational independence or a component of such project and that can be completed and implemented with funding under this NOFO as a part of the total project cost together with other, non-Federal sources (See Section C for more information).

3. Award Type

a. Grants and Cooperative Agreements

FRA will make awards for projects selected under this Notice through grant agreements or cooperative agreements. Grant agreements are used when FRA does not expect to have substantial Federal involvement in carrying out the funded activity. Cooperative agreements allow for substantial Federal involvement in carrying out the agreed upon investment, including technical assistance, review of interim work products, and increased program oversight. The term ''grant'' is used throughout this document and is intended to reference funding awarded through a grant agreement, as well as funding awarded through a cooperative agreement. The funding provided under this NOFO will be made available to grantees on a reimbursable basis. Applicants must certify that their expenditures are allowable, allocable, reasonable, and necessary to the approved project before seeking reimbursement from FRA. Additionally, the grantee is expected to expend matching funds at the required percentage concurrent with Federal

funds throughout the life of the project. See an example of standard terms and conditions for FRA grant awards at: *https://www.fra.dot.gov/eLib/Details/L19057.* This template is subject to revision.

b. Letters of Intent and Phased Funding Agreements

FRA may issue Letters of Intent (LOI) or Phased Funding Agreements (PFA) to FSP applicants proposing Major Capital Projects. Applications for a Major Capital Project who are seeking an LOI or PFA must request an LOI or PFA in the Project Narrative and provide the additional information required in Section D.2.a.iii. FRA may independently determine that a project is appropriate for an LOI or PFA. FRA may also determine that a grant or cooperative agreement is the more appropriate funding vehicle for the project, or component of the project, even if a LOI or PFA is requested.

An LOI, authorized at 49 U.S.C. 24911(g)(1), is a letter from FRA to a grantee announcing an intention to obligate an amount to the grantee's Major Capital Project from future budget authority. LOIs are contingent commitments and not binding obligations of the Federal government. FRA intends to use LOIs to demonstrate its intent to provide future Final Design and Construction Lifecycle Stage funding for Major Capital Projects assuming successful completion of Project Planning and Project Development Lifecycles for the project. FRA therefore anticipates issuing LOIs primarily to projects currently in, or beginning, the Project Development Lifecycle Stage. In issuing an LOI, FRA may outline conditions or define readiness thresholds that the grantee may use to inform future funding requests for FSP funds.

A PFA, authorized at 49 U.S.C. 24911(g)(2), is an agreement associated with the obligation of an initial grant award under the Partnership Program. FRA may only enter into a PFA for highly rated Major Capital Projects. A PFA shall: (1) establish the terms of participation by the Federal Government in the project; (2) establish the maximum amount of Federal financial assistance for the project; (3) include the period of time for completing the project, even if such period extends beyond the period for which Federal financial assistance is authorized; and (4) make timely and efficient management of the project easier in accordance with Federal law.[2] FRA anticipates limiting the use of PFAs to applications that include funding for the Construction Lifecycle Stage and are scheduled to enter the Final Design or Construction Lifecycle Stage within the Inventory Period. PFAs are contingent commitments and are not financial obligations of the Federal government. However, unlike LOIs, PFAs are agreements relating to the obligation of future funds in which FRA commits to provide funding as specified in the PFA, and subject to appropriation, for the duration of the project, as long as the grantee continues to meet the terms of the PFA. For a project with a PFA, FRA will provide grant funding in phases consistent with the terms of the PFA and within the established maximum amount of Federal financial assistance for the project.

c. Concurrent Applications

DOT and FRA may be concurrently soliciting applications for transportation infrastructure projects for several financial assistance programs. Applicants may submit applications requesting funding for a particular project to one or more of these programs. In the application for funding under this NOFO, applicants must indicate the other program(s) to which they submitted or plan to submit an application for funding the entire capital project or certain project components, as well as highlight new or revised information in the application responsive to this NOFO that differs from the previously submitted application(s).

C. Eligibility Information

This section of the notice explains applicant eligibility, cost sharing and matching requirements, project eligibility, and project component operational independence. Applications that do not meet the requirements in this section will be ineligible for funding. Instructions for submitting eligibility information to FRA are detailed in *Section D* of this NOFO.

1. Eligible Applicants

The following entities are eligible applicants for all projects permitted under this notice:

(1) a State (including the District of Columbia);

(2) a group of States;

(3) an Interstate Compact;

(4) a public agency or publicly chartered authority established by one or more States; [3]

(5) a political subdivision of a State;

(6) Amtrak, acting on its own behalf or under a cooperative agreement with one or more States;

(7) a federally recognized Indian Tribe, or

(8) any combination of the entities described in (1) through (7).

The applicant is considered the project sponsor and will be the primary point of contact for the application, and if selected, the grantee of the FSP Program award.[4] If a joint application is submitted under (8) above, one of the submitting applicants must be identified as the lead applicant to serve as the primary point of contact for the application, and if selected, as the grantee of the FSP Program award.

An application submitted by Amtrak and one or more States, whether eligible under (1), (2) or (6) above, must identify the lead applicant and include a signed cooperative agreement between Amtrak and the state(s) consistent with 49 U.S.C. 24911(a)(1)(F). Applications may reference entities that are not eligible applicants (*e.g.,* a private intercity passenger rail operator) in an application as a partner in project funding or implementation, but ineligible entities may not be the lead applicant nor, if selected, the grantee. If the applicant intends to partner with an ineligible entity, that intention should be made clear in the application and a letter of support from the ineligible entity outlining its roles and responsibilities for the project must be included in the application. Eligible applicants who partner with private operators of intercity passenger rail will be the primary point of contact and the primary recipient of the award and therefore will be responsible for administering and managing Federal funds and ultimately delivering the project. Eligible applicants must have necessary agreements to implement, manage, and oversee the project with all appropriate parties and submit these agreements as supporting documents with their application.

2. Cost Sharing or Matching

FRA will evaluate the application based on the amount of Federal funds for the project requested in the application.[5] The Federal share of total

[2] Generally, prior to receiving a PFA, the project sponsor must complete the process for complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and related environmental laws for the project.

[3] See Section D(2)(a)(iv) for supporting documentation required to demonstrate eligibility under this eligibility category.

[4] In this NOFO, the terms ''applicant'' and ''project sponsor'' are used interchangeably.

[5] If an applicant's cost share agreement demonstrates the commitment of more non-Federal

costs for FSP projects funded under this notice shall not exceed 80 percent. As stated in the NEC Project Inventory, FRA will generally fund Planning and Major Backlog projects applying under this notice up to 80 percent Federal share. FRA will generally fund Capital Renewal, Stations and Improvement projects applying under this notice between 50 and 80 percent Federal share. FRA will favorably consider a higher Federal share, within this range, for: i) projects that primarily repair, replace, or rehabilitate railroad assets such as track, structures, electric traction and power systems, and communication and signal systems, to bring such assets into a state of good repair, and ii) intercity passenger rail projects or projects that improve rail service consistent with 49 U.S.C. 24911(c)(2) and provide a high proportion of intercity passenger rail benefit relative to overall project benefits. Additionally, in preparing the Capital Cost Estimate, applicants should, as appropriate, consult available FRA guidance, including FRA's cost estimate guidance documentation, ''Capital Cost Estimating: Guidance for Project Sponsors''.[6]

The non-Federal share may be comprised of public sector (*e.g.,* State or local) or private sector funding. FRA will not consider any Federal financial assistance, or any non-Federal funds already expended (or otherwise encumbered) toward the matching requirement, unless compliant with 2 CFR part 200.[7] If repaid from non-Federal sources, Federal credit assistance is considered non-Federal share. In-kind contributions, including the donation of services, materials, and equipment, may be credited as a project cost, in a uniform manner consistent with 2 CFR part 200.306.

If Amtrak is an applicant, Amtrak may use its ticket and other non-Federal revenues generated from its operations and other sources as well as funding provided by the Supplemental Appropriations under the heading ''Northeast Corridor Grants to the National Railroad Passenger Corporation'' to satisfy the non-Federal share requirements. Applicants must identify the source(s) of their matching and other funds and must clearly and distinctly reflect these funds as part of the total project cost.

Before applying, applicants should carefully review the principles for cost sharing or matching in 2 CFR 200.306. See Section D(2)(a)(iii) for required application information on non-Federal match and Section E for further discussion of FRA's consideration of matching funds in the review and selection process. FRA will approve pre-award costs consistent with 2 CFR 200.458, as applicable (see *Section D(5)).* Cost sharing or matching may be used only for authorized Federal award purposes.

3. Other

a. Project Eligibility

Only projects on the NEC Project Inventory for which an application is submitted under this NOFO will be considered for award. The following capital projects, including acquisition of real property interests, are eligible:

(1) A project to replace, rehabilitate, or repair infrastructure, equipment,[8] or a facility used for providing intercity passenger rail service to bring such assets into a state of good repair.

(2) A project to improve intercity passenger rail service performance, including reduced trip times, increased train frequencies, higher operating speeds, improved reliability, expanded capacity, reduced congestion, electrification, and other improvements, as determined by the Secretary.

(3) A project to expand or establish new intercity passenger rail service.

(4) A group of related projects described in paragraphs (1) through (3).

(5) The planning, environmental studies, and Final Design for a project or group of projects described in paragraphs (1) through (4).

For projects that are on a shared corridor with Commuter Railroad Passenger Transportation or freight transportation, applicants must clearly demonstrate how the proposed project benefits Intercity Passenger Rail Transportation and that funding the proposed project would be a reasonable investment in Intercity Passenger Rail Transportation, independent and separate from consideration of the proposed project's benefits to other transportation purposes. A project that uses rolling stock or equipment originating from a ''country of concern'' or from a state-owned enterprise, as those terms are defined under Sec. 49 U.S.C. 20171, is ineligible.

Capital Projects, as further defined in *Section A(2),* may include the acquisition of real property interests, Project Planning, Project Development, Final Design, and Construction. Pre-Construction activities are eligible for funding independently or in conjunction with proposed funding for construction.

b. Application Tracks

Applicants are not limited in the number of applications for which they seek funding. FRA expects that applications identify only one of the following tracks for an eligible project: Track 1—Planning Studies and Project Planning; Track 2—Project Development; Track 3—Final Design (FD) and Construction.

i. Track 1—Planning Studies and Project Planning:

Planning Studies include planning activities (with no associated construction), and examples include: railroad transportation market forecasting, conceptual design activities (*e.g.,* operations analysis, establishing the type and scope of capital improvements), fleet planning, cost analysis, station and facility planning, environmental resource consideration (*e.g.,* development of a purpose and need statement, preliminary alternatives analysis, identification of environmental resources and analysis of potential environmental effects), and other similar activities. Project Planning includes planning specific to a Capital Project. Examples include the development of a purpose and need study for a proposed capital project; development of conceptual design concepts that establish the type and scope of identified capital improvements; an alternative analysis identifying the costs, benefits, service option, and methodology for eliminating preliminary project alternatives; an environmental analysis that addresses resources and potential environmental effects both to natural and the human environment.

ii. Track 2—Project Development:

Track 2 consists of projects for eligible Project Development activities. Project development includes design, environmental and other studies to ensure the project is ready for Final Design and Construction. Examples include: PE activities such as development of PE drawings and specifications (scale drawings at the 30 percent design level, including track geometry as appropriate), design criteria, schematics and/or track charts that support the development of PE; work that can be funded in conjunction with developing PE, such as operations

dollars than proposed in the application, the applicant should note the distinction and confirm that the difference was intentional.

[6] The ''Capital Cost Estimating: Guidance for Project Sponsors,'' is available at: *https://www.fra.dot.gov/Page/P0926.*

[7] See Section D(2)(a)(iii) for supporting information required to demonstrate eligibility of Federal funds for use as match.

[8] The location of the equipment's primary use will determine whether it is a project located on the NEC.

modeling, surveying, project work/management plans, preliminary cost estimates, and preliminary project schedules; and activities required to complete review under NEPA and associated laws, to advance permitting processes as appropriate, and to inform economic benefits assessments. Project Development activities funded under this NOFO should result in capital projects that are sufficiently developed to support FD or Construction activities, including with respect to equipment.

iii. Track 3—FD, FD/Construction, or Construction:

Track 3 consists of projects for eligible FD and/or Construction, and project implementation and deployment activities, including with respect to equipment. Applicants must complete all necessary Project Planning and Project Development requirements for FD/Construction projects. FD funded under this track must resolve remaining uncertainties or risks associated with the design and scope of the Capital Project; address procurement processes; and update and refine the schedule, cost estimate, and plans for financing the project to reflect accurately the expected year-of expenditure costs and cash flow projections. Prior to obligation, applicants selected for funding for FD/Construction or Construction only must demonstrate the following to FRA's satisfaction: (A) PE is completed for the proposed project, resulting in project designs that are reasonably expected to conform to all regulatory, safety, security, and other design requirements, including those under the Americans with Disabilities Act (ADA); (B) NEPA is completed for the proposed project; (C) the applicant has entered into the appropriate agreements with key project partners, including infrastructure-owning entities; and (D) a Project Management Plan is complete and up-to-date for managing the implementation of the proposed project, including the management and mitigation of project risks.

D. Application and Submission Information

Required documents for the application are outlined in the following paragraphs. Applicants should, as appropriate, consult available FRA guidance when developing applications. Applicants must complete and submit all components of the application. See *Section D(2)* for the application checklist. FRA welcomes the submission of additional relevant supporting documentation, such as planning, engineering and design documentation, and letters of support from partnering organizations. Such supporting documentation will not count against the Project Narrative 25-page limit.

1. Address To Request Application Package

Applicants may access application materials at *https://www.Grants.gov* and must submit all application materials in their entirety through *https://www.Grants.gov* no later than 5 p.m. ET, on March 27, 2023. Applicants must complete an Authorized Organization Representative (AOR) profile on *www.Grants.gov* and create a username and password. Additional information about the registration process is available at: *https://www.grants.gov/web/grants/applicants/organization-registration.html.*

Applicants are strongly encouraged to apply early to ensure that all materials are received before the application deadline. FRA reserves the right to modify this deadline. General information for submitting applications through *Grants.gov* can be found at: *https://railroads.dot.gov/grant-administration/applying-grants/competitive-grants-application-process.*

FRA is committed to ensuring that information is available in appropriate alternative formats to meet the requirements of persons who have a disability. If you require an alternative version of files provided, please contact Laura Mahoney, Office of the Chief Financial Officer, Federal Railroad Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; email: *laura.mahoney@dot.gov;* telephone: 202–578–9337.

The E-Biz POC at the applicant's organization must respond to the registration email from *Grants.gov* and login at *www.Grants.gov* to authorize the applicant as the AOR. Please note there can be more than one AOR for an organization.

If an applicant experiences difficulty at any point during this process, please call the *Grants.gov* Customer Center Hotline at 1–800–518–4726, 24 hours a day, 7 days a week (closed on Federal holidays). For information and instructions on each of these processes, please see instructions at: *https://www.grants.gov/web/grants/applicants/apply-for-grants.html.*

2. Content and Form of Application Submission

FRA strongly advises applicants to read this section carefully. Applicants must submit all required information and components of the application package to be considered for funding. Applications that are not submitted on time or do not contain all required documentation will not be considered for funding. To support the application, applicants may provide other relevant and available optional supporting documentation that may have been developed by the applicant, especially such documentation that demonstrates completion of appropriate Lifecycle Stage(s) of a Capital Project. Additionally, applicants selected to receive funding must satisfy the requirements in 49 U.S.C. 229003 and 22905, including FRA's Buy America requirement and conditions explained in part at *https://www.fra.dot.gov/page/P0185* and further in section F.2 of this notice.

All forms needed for the electronic application process are at *www.Grants.gov.* Applicants must submit the following with their application packages. The required attachments and *Grants.Gov* generated forms are outlined in the checklists below. Applications that do not complete and submit each of the required documents below will be considered incomplete and will not be reviewed.

Required Attachments

1. Project Narrative (see D.2.a)
2. Grant Template Attachments 2–5 (see D.2.b.i)
3. Funding Commitment Supporting Documentation (see D.2.a.iii)
4. Financial Plan or Funding Plan (see D.2.a.x.B.3)
5. Draft Agreement required under 49 U.S.C. 22905(c)(1), if applicable (see D.2.b.ii)

Grants.Gov Generated Forms Required (MUST BE SIGNED)

A. SF424—Application for Federal Assistance
B. SF 424A—Budget Information for Non-Construction (for an equipment procurement project or non-Construction project) OR SF 424C—Budget Information for Construction
C. FRA's F 251—Applicant Financial Capability Questionnaire
D. FRA's F 30—Certifications Regarding Debarment, Suspension and Other Responsibility Matters, Drug-Free Workplace Requirements and Lobbying
E. SF LLL—If reportable lobbying activities exist, Certification Regarding Debarment, Suspension and Other Responsibility Matters, Drug Free Workplace Requirements and Disclosure of Lobbying Activities
F. SF 424B—Assurances for Non-Construction (for an equipment procurement project or non-

Construction project) OR SF 424D—Assurances for Construction

a. Project Narrative

This section describes the minimum content required in the Project Narrative. The Project Narrative must follow the basic outline below to address the program requirements and assist evaluators in locating relevant information.

i. Cover Page	See D.2.a.i.
ii. Project Summary	See D.2.a.ii.
iii. Project Funding	See D.2.a.iii.
iv. Applicant Eligibility Criteria.	See D.2.a.iv.
v. Project Eligibility Criteria	See D.2.a.v.
vi. Detailed Project Description.	See D.2.a.vi.
vii. Project Location	See D.2.a.vii.
viii. Grade Crossing Information, if applicable.	See D.2.a.viii.
ix. Statutory Criteria	See D.2.a.ix.
x. Evaluation and Selection Criteria.	See D.2.a.x.

The above content must be provided in a narrative statement submitted by the applicant. The Project Narrative may not exceed 25 pages in length (excluding cover page, table of contents, and supporting documentation). FRA will not review or consider any pages within the Project Narratives beyond the 25-page limitation. If possible, applicants should submit supporting documents via website links rather than hard copies. If supporting documents are submitted, applicants must clearly identify the relevant portion of the supporting document with the page numbers of the cited information in the Project Narrative. The Project Narrative must adhere to the following outline.

i. *Cover Page:* Include a cover page that lists the following elements in either a table or formatted list:

Project Name	
Lead Applicant Name/Project Sponsor.	
Amount of Federal Funding Requested in this Application.	
Proposed Non-Federal Match.	
Total Project Cost/Total Project Cost For Lifecycle Stage beginning by 2024	$__/$__
LOI/PFA Requested?	Yes/No.
If PFA Funding Requested, Provide Amount of:	
—Request under this NOFO for initial obligation	Initial Obligation:
—Request under this NOFO for scheduled obligations under a PFA (This equals the remaining amount of the Total Project Cost.).	Total Future Obligations:
The above amounts combined should equal the Total Project Cost.	
If LOI Requested, Provide Amount of:	
—Request under this NOFO for obligation and	Obligation Amount:
—Requested amount under LOI which may be applied for under future NOFOs (This may or may not equal the remaining amount of the Total Project Cost.).	LOI Amount:
Was a Federal Grant Application Previously Submitted for this Project?	Yes/No.
If Yes, State the Name of the Federal Grant Program and Title of the Project in the Previous Application	Federal Grant Program:
Current Project Lifecycle Stage.	
Project Lifecycle Stage(s) to be Funded in this Application.	
Intercity Passenger Rail Service(s) Benefiting from the Project.	
For shared benefit projects, identify the Commuter Rail Passenger Transportation service(s) benefiting from the project.	
Infrastructure Owner(s) of Project Assets.	
City(-ies), State(s) Where the Project is Located.	
Congressional District(s) Where the Project is Located.	

ii. *Project Summary:* Provide a brief (4–6 sentence) summary of the proposed project and what the project will entail. Include challenges the proposed project aims to address and summarize the intended outcomes and anticipated benefits that will result from the proposed project.

iii. *Project Funding:*

a. Indicate in table format the amount of Federal funding requested under this NOFO, the proposed non-Federal match, and total project cost based on the Capital Cost Estimate. Applications for a Major Capital Project seeking funding for Construction, must include the remaining budget needed to complete the Construction Lifecycle Stage, whether or not the applicant is seeking a PFA. Applications for a Major Capital Project seeking funding for Project Development must distinguish the amount requested under this NOFO and the amount for the LOI to be requested under future NOFOs. The Capital Cost Estimate must be based on the best available information as indicated in cited references that include engineering studies, economic feasibility studies, environmental analyses, and information on the expected use of equipment or facilities.

Identify the source(s) of matching and other funds, and clearly and distinctly reflect these funds as part of the total project cost in the application budget. Include funding commitment letters outlining funding agreements, as attachments or in an appendix. Funding commitments must be signed by an authorized representative of the entity providing a non-Federal match. If Federal funding is proposed as match, demonstrate the applicant's determination of eligibility for such use, and the legal basis for that determination. Also, note if the requested Federal funding under this NOFO or other programs must be obligated or spent by a certain date due to dependencies or relationships with other Federal or non-Federal funding sources, related projects, law, or other factors. If applicable, provide the type and estimated value of any proposed in-kind contributions, as well as substantiate how the contributions meet the requirements in 2 CFR 200.306.

Finally, specify whether Federal funding for the project has previously been sought, and identify the Federal program and fiscal year of the funding request(s), as well as highlight new or revised information in the FSP application that differs from the application(s) to other financial assistance programs. FRA may not award more funding for a project than is requested in an application.

b. Example Project Funding Tables:

The following tables provide examples of how applicants may provide project funding information. All applicants should provide the information requested in Table 1 and Table 2. Only applicants with Major Capital Projects are required to provide the information requested in all three

tables. Applicants may provide additional rows and columns, or additional project funding tables, as appropriate, to provide the requested project funding information.

TABLE 1—PROJECT COST BY TASK

Task No.	Task name/ project component	Non-federal funding		FSP funding request		Other federal funding		Total ($)
		Amount ($)	Percent (%)	Amount ($)	Percent (%)	Amount ($)	Percent (%)	
1	.....	.....	.....	.....	.....	.....	.....	.....
2	.....	.....	.....	.....	.....	.....	.....	.....
3	.....	.....	.....	.....	.....	.....	.....	.....

TABLE 2—SOURCE OF FUNDS

Type	Source	Amount ($)	Percent of project cost (%)
Federal	FSP Funds Request	.....	.....
	FSP PFA or LOI Request	.....	.....
	Other Federal Funds	.....	.....
Non-Federal	Non-Federal Matching Funds	.....	.....

TABLE 3—PROJECT COSTS BY ANTICIPATED YEAR OF EXPENDITURE

	FY 2023	FY 2024	FY 2025	FY 2026
FSP Funding	.....	.....	.....	.....
Other Federal	.....	.....	.....	.....
Non-Federal	.....	.....	.....	.....
Total	.....	.....	.....	.....

c. Applications for a Major Capital Project seeking funding for FD/Construction or Construction Stage activities that are scheduled to enter the Final Design or Construction Stages within the Inventory Period, must provide an annualized budget in year of expenditure dollars, the anticipated annual Federal funding requests from this grant program, anticipated future non-Federal match, and total project cost through completion of the Construction Stage, so that FRA can properly evaluate the project for a PFA. PFA applicants must include proposed milestones by which FRA can measure progress.

iv. *Applicant Eligibility Criteria:* Explain how the applicant meets the applicant eligibility criteria outlined in *Section C* of this notice. For public agencies and publicly chartered authorities established by one or more States, the explanation must include relevant legislative language and citations to the applicable enabling legislation. Include the technical qualifications and demonstrated experience of key personnel proposed to lead and perform the technical efforts, and the qualifications of the primary and supporting organizations to fully and successfully execute the proposed project within the proposed timeframe and budget. Discussion of applicant qualifications should include experience in managing similar projects and specifically address the considerations in 2 CFR 200.206(b).

For applications involving Amtrak and one or more States, Amtrak and the State(s) must provide a cooperative agreement for the project signed by authorized representatives of Amtrak and each State. Such cooperative agreements must include a description of the roles and responsibilities of each party, including budget and subrecipient information showing how the parties will share project costs. A cost share agreement signed by Amtrak and one or more States would address this requirement if it addressed the requirements above.

v. *Project Eligibility Criteria:* Demonstrate that the proposed project meets the project eligibility criteria in *Section C(3)(a)* of this notice.

vi. *Detailed Project Description:* Include a detailed project description that expands upon the project summary. The detailed description should provide, at a minimum: a statement of the intercity passenger rail benefit of the project and the proportion of intercity passenger rail benefit relative to overall project benefits; a statement of the purpose or purposes for undertaking the project consistent with 49 U.S.C. 24911(c)(1–5), including identifying the primary purpose of the project or the relative importance of such purposes; a thorough description of the scope of the project identifying the specific components and elements of the project and associating those components and elements to the purposes provided above; additional background on the transportation challenges the project aims to address; a summary of current and proposed railroad operations in the project area, to include identification of all railroad owners and operators, typical daily, weekly, or annual train counts by operator, and ridership data for passenger operations; a statement of the primary expected project outcomes such as increased ridership, reduced delays, improved rail network asset condition and performance, or similar outcomes and benefits; identification of the expected users and beneficiaries of the project, including all railroad operators and types of passenger or freight rail service operating or proposed to operate in the project area; a statement demonstrating how the proposed project is consistent with the NEC Planning Documents [9] and

[9] Applicants may submit copies of the relevant pages of such plans as supporting documents in

associated state or regional long-range planning documents and local government priorities; and any other information the applicant deems necessary to justify the proposed project.

vii. *Project Location:* Include geospatial data for the project, as well as a map of the project's location. Geospatial data can be expressed in terms of decimal degrees for latitude and longitude of at least five decimal places of precision or start and end mileposts with the railroad code of the owning railroad and subdivision name. On the map, include the Congressional districts in which the project will take place.

viii. *Grade Crossing Information, if applicable:* For a project that includes grade crossing components, cite specific DOT National Grade Crossing Inventory information, including the railroad that owns the infrastructure (or the crossing owner, if different from the railroad), the primary railroad operator, the DOT crossing inventory number, and the roadway at the crossing. Applicants can search for data to meet this requirement at the following link: *https://railroads.dot.gov/safety-data/fra-safety-data-reporting/crossing-inventory-data-search.*

ix. *Statutory Criteria:* Include a statement that the proposed project is consistent with the most recently published NEC Project Inventory, or in the alternative include a statement that there have not been any material changes to infrastructure, service conditions or project sponsor capabilities or commitments or other significant changes that may affect the scope, schedule or budget of the project, or in the alternative a statement explaining such material changes and how they will affect the scope, schedule or budget of the project.

For projects that benefit intercity and commuter rail services, a statement that Amtrak and the public authorities providing commuter rail passenger transportation at the eligible project location are in compliance with section 24905(c)(2); and identification of the funding for the intercity passenger rail share, the commuter rail share and the local share of the project before commencement of the project. Applicants must identify these shares for the Lifecycle Stage(s) for which they are seeking funding (for example, an application seeking funding only for Project Development must identify funding shares only for the Project Development Lifecycle Stage and not for the FD and Construction stages of the same project.)

x. Evaluation and Selection Criteria: Include a thorough discussion of how the proposed project meets the evaluation and selection criteria as outlined in Section E of this notice. If an application does not sufficiently address the evaluation criteria and the selection criteria, it is unlikely to be a competitive application.

A. *Project Implementation:*

Describe proposed project implementation and project management arrangements. Applicants must address whether railroad workforce needs have been evaluated as well as whether all required resources have been identified. Include descriptions of the arrangements for handling work force constraints and outages, project contracting including use of small businesses consistent with 2 CFR 200.321, contract oversight and control, change-order management, and conformance to Federal requirements for project progress reporting (see *https://www.fra.dot.gov/Page/P0274*). Further, applicants must provide their plan for taking affirmative steps to employ small businesses consistent with 2 CFR 200.321.

Assessment of Project Risks and Mitigation Strategies. Project risks, such as procurement delays, environmental uncertainties, increases in real estate acquisition costs, uncommitted local match, concerns expressed by stakeholders or impacted communities or residents or businesses who would be relocated for the project, or lack of legislative approval, affect the likelihood of successful project start and completion. Applicant must identify all material risks to the project and the strategies that the lead applicant and any project partners have undertaken or will undertake to mitigate those risks. The applicant will assess the greatest risks to the project and identify how the project parties will mitigate those risks. The applicant must include its risk monitoring, management and mitigation strategy and explain management staffing plans and procedures. Risks and mitigation strategies should be summarized in the project narrative and additional detailed information should be provided with the application as supporting documentation.

Provide a Project Management Plan including management controls, relations management, project planning and concept design, description and approach to managing risk, environment, design management, project delivery, construction management, construction close out, start up and revenue operation, real estate acquisition and management, and rolling stock acquisition and management (see *https://railroads.dot.gov/training-guidance/resources/project-development*).

B. *Project Readiness:*

1. *Lifecycle Stage*

Applicants should demonstrate completion of the Project Lifecycle prerequisites consistent with the definitions of Lifecycle Stages and consistent with the available guidance at the time of application.[10]

For Planning Studies projects (to be submitted under Track 1), applicants must state why the planning study is being undertaken (*e.g.,* to advance a Departmental strategic goal, to advance the NEC toward achieving a state of good repair, or to study how trip times on the NEC can be improved), and the primary activities to be undertaken in the planning study (*e.g.,* feasibility study, a market analysis, a preliminary alternatives analysis, stakeholder coordination effort). Applicants should demonstrate the extent of support from local, regional, State or other partners to advance the study.

For Planning Projects (to be submitted under Track 1), applicants should demonstrate whether there is support from local, regional, State or other partners to advance the study. For projects currently in a planning stage, applicants should indicate whether preliminary alternatives have been developed, evaluated and submitted for public review and comment, as well as the timeline for procurement of preliminary engineering services.

For Project Development projects (to be submitted under Track 2), applicants must indicate whether or the extent to which the following has been completed or provide the timeline for completion: development of a purpose and need statement; development of preliminary alternatives; public, tribal and agency outreach regarding the project; and development of conceptual design.

For Final Design projects, Final Design and Construction projects, or Construction projects (to be submitted under Track 3), applicants must indicate whether Project Development activities, including issuance of a NEPA decision by a USDOT agency, acceptance of preliminary engineering by FRA, and preparation of a project management plan have been completed, or provide

their application or provide a citation of the relevant document name(s) and page number(s).

[10] FRA published the proposed Guidance on Development and Implementation of Railroad Capital Projects in the **Federal Register** on June 28, 2022. 87 FR 38451; FRA Docket No. FRA–2022–0035. FRA anticipates that the final Guidance will be published in the **Federal Register** soon. The final Guidance will also be made available on FRA's website and in FRA Docket No. FRA–2022–0035.

the timeline for completion. In addition, applicants must describe the status of coordination among FRA and the operating railroads in the study area in relation to track configuration. If coordination is complete, provide documentation of operator and FRA's concurrence with the new track configuration. For Construction projects, the applicant must demonstrate completion of final design documentation that is consistent with the NEPA decision, and the engineering configuration accepted during Project Development.

2. *Status of Environmental Review.*

Applicants should explain what Federal (and, if appropriate, State and local) environmental compliance and permitting requirements have been completed. Such requirements include NEPA and other Federal, local and State permitting requirements, if applicable. If the NEPA process is complete, an applicant should indicate the date of completion, and provide a website link or other reference to the NEPA decision document, which might include a final Categorical Exclusion, Finding of No Significant Impact, or Record of Decision. If the NEPA process is not yet underway, the application should state this. If the NEPA process is underway, but not complete, the application should detail the type of NEPA review underway, where the project is in the process, and indicate the anticipated date of completion of all NEPA-related milestones. If the last agency NEPA document was dated more than three years before the application date, the applicant should explain whether the NEPA document needs to be updated and include a proposed approach, if appropriate, for such an update in accordance with applicable NEPA and FRA requirements as well as indicate what, if any, coordination on the update has been conducted with FRA. Information regarding FRA's environmental processes and requirements are located at *https://www.fra.dot.gov/environment.* For all other Federal, state and local permitting requirements, the applicant should describe which permits apply, the status of those reviews, and the expected timeline for completion.

3. *Financial Readiness.*

Applicants must provide a funding plan consistent with the project budget identifying anticipated sources of project funding, describing the applicant's assessment of financial risk to the project and mitigation strategies, providing a methodology for handling cost overruns, and determining and analyzing appropriate contingency. The funding plan must also describe the applicant's plan for financing operation and maintenance of the project. If selected, a financial plan for Major Capital Projects must be prepared consistent with the requirements of the Final Railroad Capital Project Development and Implementation Guidance by time of obligation.

For anticipated Federal funding other than through the FSP Program, describe when the funding is expected to be secured and indicate what federal grant programs are anticipated, as well as the percentage of the total project cost expected be funded by the other federal funds.

For anticipated non-Federal funding, applicants must provide the total percentage of non-Federal funding and identify the sources of the non-Federal share. Applicants should demonstrate the availability of non-Federal funds for project match, for example, by including an approved budget document showing the match commitment, a funding commitment letter signed by an authorized official of the entity committing funds, or similar materials.

Applicants should provide executed cost sharing agreements if applicable, or, if incomplete, describe whether they have been started and the expected timeline for finalizing those agreements.

For Major Capital Projects, the Capital Cost Estimate should incorporate a narrative and Risk Assessment consistent with the available guidance at the time of application and that describes and explains the logic, methods, assumptions, and calculations used in the estimate, and should account for varying risks related to materials, labor, and project activities necessary for an independently conducted risk review.

4. *Legal, financial and technical capacity of the applicant.*

i. Legal capacity of applicant.

To address legal capacity, an applicant should indicate whether it owns now or will own the project property and provide a description of agreements necessary to enable the project construction, necessary continuing access and ability to ensure operation and maintenance.

ii. Financial capacity of applicant.

To explain financial capacity, applicants should complete FRA Form 251. Describe past experience in managing and overseeing similar projects.

iii. Technical capacity of applicant.

To explain technical capacity applicants should demonstrate experience of key personnel proposed to lead and perform the technical efforts, and the qualifications of the primary and supporting organizations to fully and successfully execute the proposed project within the proposed time frame and budget. Discussion of applicant qualifications should include experience in managing similar projects and specifically address the considerations in 2 CFR 200.206(b) including the applicant's financial stability, management systems and standards, history of performance, audit reports and findings, and ability to effectively implement grant requirements. Include the technical qualifications and demonstrated experience of key personnel proposed to lead and perform the technical efforts, and the qualifications of the primary and supporting organizations to fully and successfully execute the proposed project within the proposed timeframe and budget.

C. *DOT Strategic Goals:* In addressing the selection criteria applicants must address the following:

a. *Safety:* The applicant must, if applicable, include information on, and to the extent possible, quantify, how the project will target known documented safety problems within the project area or wider rail network and demonstrate how the project will address safety risks. A project addressing grade crossings should include specific DOT National Grade Crossing Inventory information, including the railroad that owns the infrastructure (or the crossing owner, if different from the railroad), the primary railroad operator, the DOT crossing inventory number, and the roadway at the crossing. Applicants can search for data to meet this requirement at the following link: *https://safetydata.fra.dot.gov/OfficeofSafety/default.aspx.* In addition, if applicable, applicants should provide the page number in the State Highway-Rail Grade Crossing Action Plan where the grade crossing is referenced. Applicants should specify whether the project will result in the elimination of one or more grade crossings through grade separation or otherwise. the number of crossings addressed and focus on what the project intervention will do to mitigate existing quantifiable safety problems. The application should provide evidence to support the claimed level of effectiveness of the project in protecting motorized and non-motorized travelers from health and safety risks, such as the number or rate of crashes, serious injuries, and/or fatalities. In cases which the project seeks to upgrade infrastructure, the applicant is encouraged to describe the infrastructure being upgraded and specifically how the upgrades enhance safety with documentation provided.

b. *Economic Strength and Global Competitiveness:* The applicant must, if applicable, include information on, and to the extent possible, quantify, how the project will target known documented issues or improve conditions for laborers and/or local residents in regard to equitable economic strength and core assets within the project area or wider rail network. Quantifiable elements corresponding to this DOT objective may include specific commitment regarding targeted hiring or utilization of underrepresented workers written into the process or labor agreement(s) of the project, the creation of long-term employment opportunities with estimated quantity range expressed as a number or demonstrate how the project will contribute to economic progress stemming from infrastructure investment. To the extent that applicants have not sufficiently considered job quality and labor rights in their planning, as determined by the Department of Labor, the applicants will be required to do so before receiving funds for construction, consistent with Executive Order 14025, *Worker Organizing and Empowerment* (86 FR 22829), and Executive Order 14052, *Implementation of the Infrastructure Investment and Jobs Act* (86 FR 64335). Specifically, the project planning activities and project delivery actions must support: (a) strong labor standards and the free and fair choice to join a union, including project labor agreements, local hire agreements, distribution of workplace rights notices, and use of an appropriately trained workforce; (b) high-quality workforce development programs, including registered apprenticeship, labor-management training programs, and supportive services to help train, place, and retain people in good-paying jobs and apprenticeships; and (c) comprehensive planning and policies to promote hiring and inclusion for all groups of workers, including through the use of local and economic hiring preferences, linkage agreements with workforce programs that serve these underrepresented groups, and proactive plans to prevent harassment. Consistent with E.O. 11246, *Equal Employment Opportunity* (30 FR 12319, and as amended), all federally assisted contractors are required to make good faith efforts to meet the goals of 6.9 percent of construction project hours being performed by women, in addition to goals that vary based on geography for construction work hours and for work being performed by people of color.

c. *Equity:* The applicant must, if applicable, include information on, and to the extent possible, quantify, how the project will target known documented inequality and barriers to opportunity within the project area or wider rail network. Quantifiable elements corresponding to this DOT objective may include specific ways the project supports investments increasing accessibility to rail infrastructure and expanding travel options for underserved populations by providing data on the size of the targeted underserved population, demographic descriptors of the population, and distance from project area to key locations. If applicable, the applicant should describe how the project will meet ADA requirements and be accessible to people with disabilities, including individuals who use wheelchairs, and how the project will connect underserved communities to essential services such as hospitals, grocery stores, or affordable housing. If applicable, applicants should include their plan for taking affirmative steps to employ small business consistent with 2 CFR 200.321, workforce development and training information, if applicable: For any project that includes workforce development, applicants must document, to the extent practicable, similar existing local training programs supported by the DOT, the Department of Labor, and/or the Department of Education. The applicant must also (a) describe whether the workforce development project incorporates union representation, and (b) describe any involvement or partnership with existing in-house skills training programs, unions and worker organizations, community colleges and public school districts, community-based organizations, supportive services providers, pre-apprenticeships tied to Registered Apprenticeships, Registered Apprenticeship programs and other labor-management training programs, or other quality workforce training providers. FRA strongly encourages applicants to outline their plan to recruit, train, and retain a locally hired, diverse workforce. In support of Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* (86 FR 7009) and Executive Order 14008, FRA will assess the project's ability to address equity and barriers to opportunity, to the extent possible within the program and consistent with law. Such considerations will include, but are not limited to, the applicant's plan for using small businesses to complete its project, the extent to which the project improves or expands transportation options for underserved communities, mitigates the safety risks and detrimental quality of life effects that rail lines can have on communities especially those communities that might have been historically disconnected due to the railroad infrastructure, and expands workforce development and career pathway opportunities to foster a more diverse rail industry. This will also include community engagement efforts already taken or planned, the extent to which engagement efforts are designed to reach impacted communities, whether engagement is accessible for persons with disabilities or limited English proficient persons within the impacted communities, and how community feedback is taken into account in decision-making.[11]

d. *Climate and Sustainability:* The applicant must, if applicable, include information on, and to the extent possible, quantify, how the project will target climate change and sustainability within the project area or wider rail network. Quantifiable elements corresponding to this DOT objective may include specific data showing expected shift to different transportation modes, reduction in fossil fuel usage or greenhouse gas (GHG) emissions from project implementation, and programmatic infrastructure review showing existing infrastructure or evacuation vulnerabilities to climate change events. Projects that have not sufficiently considered climate change and sustainability in their planning, as determined by FRA, will be required to do so before receiving funds for construction, consistent with Executive Order 14008 In the grant agreement, recipients will be expected to describe activities they have taken or will take prior to obligation of construction funds that addresses climate change and environmental justice (EJ). Activities that address climate change include, but are not limited to, demonstrating: the project will result in significant GHG emissions reductions; and the project supports emissions reductions goals in a Local/Regional/State plan. Activities that address EJ include but are not limited to: basing project design on the results of a proven EJ screening tool (developed by another Federal agency such as the EPA, a state agency, etc.);

[11] For more information and best practices on meaningful public involvement applicants are encouraged to review the DOT's Promising Practices for Meaningful Public Involvement in Transportation Decision-Making at *https://www.transportation.gov/priorities/equity/promising-practices-meaningful-public-involvement-transportation-decision-making*).

conducting enhanced, targeted outreach to EJ communities; considering EJ in alternatives analysis and final project design; and supporting a modal shift in freight or passenger movement to reduce emissions or reduce induced travel demand.

e. *Transformation.* The applicant must, if applicable, provide information on and, to the extent possible, quantify, how the project will transform the nation's transportation infrastructure within the project area or wider rail network to improve operations, increase capacity, and maintain existing assets. Quantifiable elements corresponding to this DOT objective may include data showing additional capacity of the rail system in terms of passengers served, programmatic review of existing assets showing vulnerability due to age or lack of maintenance, and change of maintenance requirements (*i.e.,* hours spent with a train or rail line taken out of operation to make maintenance repairs before and after the project).

b. Additional Application Elements

Applicants must submit:

i. Grant Template Attachments 2–5: A Statement of work (SOW) addressing the scope, a schedule, a budget, and performance measures for the proposed project if it were selected for award as described in Section F(3)(c) and required in 2 CFR 200.301. The four required templates are labeled ''Example General Grants—Attachments 2–5'' and are located at *https://www.fra.dot.gov/Page/P0325.* Applications that do not complete and submit all four of the grant package templates will be considered incomplete and will not be reviewed. The SOW must contain sufficient detail so FRA, and the applicant, can understand the expected outcomes of the proposed work to be performed and can monitor progress toward completing project tasks and deliverables during a prospective grant's period of performance.

ii. Draft Agreement required under 49 U.S.C. 22905(c)(1), if applicable. As a condition of receiving a grant under this program for a project that uses rights-of-way owned by a railroad, the grantee shall have in place a written agreement between the grant recipient and the railroad regarding such use and ownership, including any compensation for such use; assurances regarding the adequacy of infrastructure capacity to accommodate both existing and future freight and passenger operations; an assurance by the railroad that collective bargaining agreements with the railroad's employees including terms regulating the contracting of work will remain in full force and effect according to their terms for work performed by the railroad on the railroad transportation corridor; and an assurance that the grant recipient complies with liability requirements consistent with 49 U.S.C. 28103. For additional information please see FRA's Answers to Frequently Asked Questions about Rail Improvement Grant Conditions under 49 U.S.C. 22905(c)(1).[12]

3. Unique Entity Identifier and System for Award Management (SAM)

To apply for funding through *Grants.gov,* applicants must be properly registered in SAM before submitting an application, provide a valid unique entity identifier in its application, and continue to maintain an active SAM registration all as described in detail below. Complete instructions on how to register and submit an application can be found at *www.Grants.gov.* Registering with *Grants.gov* is a one-time process; however, it can take up to several weeks for first-time registrants to receive confirmation and a user password. FRA recommends that applicants start the registration process as early as possible to prevent delays that may preclude submitting an application package by the application deadline. Applications will not be accepted after the due date. Delayed registration is not an acceptable justification for an application extension.

FRA may not make a grant award to an applicant until the applicant has complied with all applicable SAM requirements and if an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Late applications, including those that are the result of a failure to register or comply with *Grants.gov* applicant requirements in a timely manner, will not be considered. If an applicant has not fully complied with the requirements by the submission deadline, the application will not be considered. To submit an application through *Grants.gov*, applicants must:

a. Register with the SAM at *www.SAM.gov*

All applicants for Federal financial assistance must maintain current registrations in the SAM database. An applicant must be registered in SAM to successfully register in *Grants.gov.* The SAM database is the repository for standard information about Federal financial assistance applicants, grantees, and subrecipients. Organizations that have previously submitted applications via *Grants.gov* are already registered with SAM, as it is a requirement for *Grants.gov* registration. Please note, however, that applicants must update or renew their SAM registration at least once per year to maintain an active status. Therefore, it is critical to check registration status well in advance of the application deadline. If an applicant is selected for an award, the applicant must maintain an active SAM registration with current information throughout the period of the award, including information on a grantee's immediate and highest level owner and subsidiaries, as well as on all predecessors that have been awarded a Federal contract or grant within the last three years, if applicable. Information about SAM registration procedures is available at *www.sam.gov.*

b. Obtain a Unique Entity Identifier

On April 4, 2022, the Federal government discontinued using DUNS Numbers. The DUNS Number was replaced by a new, non-proprietary identifier that is provided by the System for Award Management (SAM.gov). This new identifier is called the Unique Entity Identifier (UEI), or the Entity ID. To find or request a Unique Entity Identifier, please visit *www.sam.gov.*

4. Submission Dates and Times

Applicants must submit complete applications to *www.Grants.gov* no later than 5:00 p.m. ET, March 27, 2023. Applicants will receive a system-generated acknowledgement of receipt. FRA reviews *www.Grants.gov* information on dates/times of applications submitted to determine timeliness of submissions. Late applications will be neither reviewed nor considered. Delayed registration is not an acceptable reason for late submission. To apply for funding under this announcement, all applicants are expected to be registered as an organization with *Grants.gov.* Applicants are strongly encouraged to apply early to ensure all materials are received before this deadline.

To ensure a fair competition of limited discretionary funds, no late submissions will be reviewed for any reason, including: (1) failure to complete the *Grants.gov* registration process before the deadline; (2) failure to follow *Grants.gov* instructions on how to register and apply as posted on

[12] *https://railroads.dot.gov/sites/fra.dot.gov/files/2022-05/Rail-Improvement-Grant-Conds%20-Sec22905-FAQs_042922.pdf.*

its website; (3) failure to follow all the instructions in this NOFO; and (4) technical issues experienced with the applicant's computer or information technology environment.

5. Intergovernmental Review

Intergovernmental Review is required for this program. Applicants must contact their State Single Point of Contact to comply with their state's process under Executive Order 12372.

6. Funding Restrictions

Consistent with 2 CFR 200.458, as applicable, FRA will only approve pre-award costs if such costs are incurred pursuant to the negotiation and in anticipation of the grant agreement and if such costs are necessary for efficient and timely performance of the scope of work. Under 2 CFR 200.458, grant recipients must seek written approval from FRA for pre-award activities to be eligible for reimbursement under the grant. Activities initiated prior to the execution of a grant or without FRA's written approval may be ineligible for reimbursement or matching contribution. Cost sharing or matching may be used only for authorized Federal award purposes.

FRA is prohibited under 49 U.S.C. 22905(f) [13] from providing FSP grants for Commuter Rail Passenger Transportation. FRA's interpretation of this provision is informed by the language in 49 U.S.C. 24911, and specifically the eligible capital projects in 49 U.S.C. 24911(c). FRA's primary intent in funding FSP projects is to make reasonable investments in Capital Projects for Intercity Rail Passenger Transportation. Such projects may be located on shared corridors where Commuter Rail Passenger Transportation and/or freight rail also benefit from the project.

7. Other Submission Requirements

For any supporting application materials that an applicant cannot submit via *Grants.gov*, such as oversized engineering drawings, an applicant may submit an original and two (2) copies to Mr. Bryan Rodda, Amtrak and Northeast Corridor Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–203, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, FRA advises applicants to use other means of conveyance (such as courier service) to assure timely receipt of materials before the application deadline. Additionally, if documents can be obtained online, explaining to FRA how to access files on a referenced website may also be sufficient.

Note: Please use generally accepted formats such as .pdf, .doc, .docx, .xls, .xlsx and .ppt, when uploading attachments. While applicants may embed picture files, such as .jpg, .gif, and .bmp in document files, applicants should not submit attachments in these formats. Additionally, the following formats will not be accepted: .com, .bat, .exe, .vbs, .cfg, .dat, .db, .dbf, .dll, .ini, .log, .ora, .sys, and .zip.

E. Application Review Information

1. Criteria: Eligibility, Completeness and Application Risk Review

FRA will first screen each application for applicant and project eligibility (eligibility requirements are outlined in *Section C* of this notice), completeness (application documentation and submission requirements are outlined in *Section D* of this notice), and the 20 percent minimum non-Federal match.

FRA will determine whether the proposed project is consistent with the most recently published NEC Project Inventory, and if not whether materially changed infrastructure or service conditions, changes in project sponsor capabilities or commitments, or other significant changes since the completion of the most recently published NEC Project Inventory have occurred. For projects that benefit intercity and commuter rail services, FRA will determine whether Amtrak and the public authorities providing commuter rail passenger transportation at the eligible project location: are in compliance with section 24905(c)(2); and have identified funding for the intercity passenger rail share, the commuter rail share, and the local share of the eligible project before the commencement of the project. Applicants must identify these shares for the Lifecycle Stage(s) for which they are seeking funding (for example, an application seeking funding only for Project Development must identify funding shares only for the Project Development Lifecycle Stage and not for the FD and Construction stages of the same project.)

a. Evaluation Criteria

Consistent with the NEC Project Inventory, FRA's first priority will be selecting Major Backlog projects and Planning Studies. FRA's second priority will be selecting other projects in or beginning the Final Design or Construction Lifecycle Stages within the Inventory Period. FRA will evaluate all eligible and complete applications using the following evaluation criteria.

i. Technical Merit: FRA will take into account—

A. The degree to which the application, statement of work, schedule and budget are reasonable and appropriate to achieve the expected outcomes of the proposed project on time and on budget;

B. The extent to which the proposed implementation approach demonstrates an efficient project delivery approach, demonstrates the commitment of necessary resources and workforce to deliver the project in accordance with the proposed schedule and budget, and includes methods for handling track outages to reduce service impacts and maximize productivity during such outages (*e.g.,* construction is coordinated with other geographically proximate projects);

C. Project Readiness: FRA will evaluate the extent to which the project demonstrates strong project readiness by:

i. *Lifecycle Stage.* Completion of all prerequisites necessary to reach the scheduled Lifecycle Stage(s) proposed for funding in the application and consistent with the Lifecycle Stage(s) anticipated to start during the Inventory Period;

ii. *Status of Environmental Review.* Status of environmental and permitting approval(s) and likelihood of any outstanding approval(s) affecting project obligation or completion;

iii. *Technical Capacity.* Demonstration of capacity to successfully deliver the project in compliance with applicable Federal requirements including whether the applicant has, or will have

(a) the legal, financial and technical capacity to carry out the project,

(b) satisfactory continuing access to the equipment or facilities, and

(c) the capability and willingness to maintain the equipment or facilities; and

iv. *Financial Readiness.* Demonstration of financial resources necessary to complete the project. For a Project where an applicant is requesting funding for the Final Design and/or Construction Lifecycle Stages of projects, FRA will assess demonstration of commitment of the financial resources to bring the project to completion.

ii. Funding Considerations:

In determining FSP Program funding allocations, FRA will generally fund Capital Renewal, Stations and Improvement projects applying under this notice between 50 and 80 percent Federal share. FRA will favorably

[13] Under 49 U.S.C. 24911(i), FSP grants are subject to the conditions in 49 U.S.C. 22905.

consider a higher Federal share, within this range, to the extent such projects:

(A) Replace, rehabilitate, or repair infrastructure, equipment, or a facility used for providing intercity passenger rail service to bring such assets into a state of good repair;

(B) Improve intercity passenger rail service performance consistent with 49 U.S.C. 24911(c)(2), and provide a high proportion of intercity passenger rail benefit relative to overall project benefits.

b. Selection Criteria

In addition, FRA will:

1. *Consider the following:*

i. The geographic diversity of the projects receiving funding, and

ii. The award of other competitive Federal funds for the project.

2. Consider the extent to which the project adequately address the following DOT Strategic Goals:

i. *Safety.* FRA will assess the project's ability to foster a safe transportation system for the movement of goods and people, consistent with the Department's strategic goal to reduce transportation-related fatalities and serious injuries across the transportation system. Such considerations will include, but are not limited to, the extent to which the project improves safety at highway-rail grade crossings, reduces incidences of rail-related trespassing, and upgrades infrastructure to achieve a higher level of safety.

ii. *Economic Strength and Global Competitiveness.* FRA will assess the project's ability to contribute to economic progress stemming from infrastructure investment and associated job creation in the industry. Such considerations will include, but are not limited to, the extent to which the project results in high-quality job creation by supporting good-paying jobs with a free and fair choice to join a union, and in on-going operations and maintenance, and incorporates strong labor standards, such as through the use of project labor agreements or union neutrality agreements; includes comprehensive planning and policies to promote hiring of underrepresented populations including local and economic hiring preferences and investments in high-quality workforce development programs with supportive services, including labor-management programs, to help train, place, and retain people in good-paying jobs or registered apprenticeship, and invests in vital infrastructure assets;

iii. *Equity.* FRA will assess the project's ability to address equity and barriers to opportunity, to the extent possible within the program and consistent with law. Such considerations will include, but are not limited to, the applicant's plan for using small businesses to complete its project, the extent to which the project improves or expands transportation options and mitigates the safety risks and detrimental quality of life effects that rail lines can have on communities. This will also include community engagement efforts already taken or planned, the extent to which engagement efforts are designed to reach impacted communities, whether engagement is accessible for persons with disabilities or limited English proficient persons within the impacted communities, and how community feedback is taken into account in decision-making.

iv. *Climate and Sustainability.* In support of Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad,* FRA will assess the project's ability to reduce the harmful effects of climate change and anticipate necessary improvements to prepare for extreme weather events. Such considerations will include, but are not limited to, the extent to which the project reduces overall lifecycle emissions, promotes energy efficiency, incorporates lower-carbon construction materials, increases resiliency, and recycles or redevelops existing infrastructure.

v. *Transformation.* FRA will assess the project's ability to expand and improve the nation's rail network, which needs to balance new infrastructure for increased capacity with proper maintenance of aging assets. Such considerations will include, but are not limited to, the extent to which the project adds capacity to congested corridors, builds new connections or attracts new users to passenger rail, and ensures assets will be improved to a state of good repair.

2. Review and Selection Process

Consistent with the NEC Project Inventory, FRA will conduct an application review process, as follows. FRA will evaluate applications for Major Backlog projects first, followed by evaluations for the remaining project types.

a. Screen applications for applicant and project eligibility, completeness, the minimum match;

b. Evaluate remaining applications (completed by technical panels applying the evaluation criteria) to:

(1) Prioritize projects based on technical merit (including readiness) consistent with the NEC Project Inventory (*e.g.,* Capital Renewal, Stations and Improvement projects starting Construction within the Inventory period will be prioritized with other Capital Renewal, Stations and Improvement projects starting Construction in the Inventory period.)

(2) Review for funding allocation considerations; and

(3) Assign a rating of ''Not Recommended'', ''Acceptable,'' ''Recommended,'' or ''Highly Recommended'';

c. Review highly rated Major Capital Projects for LOI and PFAs, as applicable, to determine whether either is appropriate for the project based on project specific characteristics, funding availability, and statutory and policy criteria stated in this NOFO, as well as review funding allocation considerations provided by the technical panels (completed by a panel of senior FRA officials.)

d. Apply selection criteria and recommend initial selection of projects consistent with the prioritization and funding allocations described in the NEC Project Inventory (including recommendations for potential PFA/LOIs and options for reduced awards) for the FRA Administrator's review (completed by a Senior Review Team, which includes senior leadership from the Office of the Secretary and FRA); and

e. Select projects for grant award and associated PFAs or LOIs for the Secretary's or his designee's review and approval (completed by the FRA Administrator).

3. Reporting Matters Related to Integrity and Performance

Before making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold of $250,000 (see 2 CFR 200.88 Simplified Acquisition Threshold), FRA will review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). See 41 U.S.C. 2313.

An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.

FRA will consider any comments by the applicant, in addition to the other information, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the

review of risk posed by applicants as described in 2 CFR 200.205.

F. Federal Award Administration Information

1. Federal Award Notice

FRA will announce applications selected for funding in a press release and on FRA's website after the application review period. This announcement is FRA's notification to successful and unsuccessful applicants alike. Project Sponsors of rail projects who are ineligible to receive Partnership Program funding, who are not selected for Partnership Program funds, or who receive less than the requested Partnership Program funding amount, are encouraged to consider other FRA and Departmental grant programs.

FRA will contact applicants with successful applications after announcement with information and instructions about the award process. This notification is not an authorization to begin proposed project activities. FRA requires satisfaction of applicable requirements by the applicant and a formal agreement signed by both the grantee and the FRA, including an approved scope, schedule, and budget, before obligating the grant. See an example of standard terms and conditions for FRA grant awards at *https://railroads.fra.dot.gov/elibrary/award-administration-and-grant-conditions.* This template is subject to revision.

2. Administrative and National Policy Requirements

In connection with any program or activity conducted with or benefiting from funds awarded under this notice, grantees of funds must comply with all applicable requirements of Federal law, including, without limitation, the Constitution of the United States; the conditions of performance, nondiscrimination requirements, and other assurances made applicable to the award of funds in accordance with regulations of DOT; and applicable Federal financial assistance and contracting principles promulgated by the Office of Management and Budget (OMB). In complying with these requirements, grantees, in particular, must ensure that no concession agreements are denied or other contracting decisions made on the basis of speech or other activities protected by the First Amendment. If DOT determines that a grantee has failed to comply with applicable Federal requirements, DOT may terminate the award of funds and disallow previously incurred costs, requiring the grantee to reimburse any expended award funds.

Examples of administrative and national policy requirements include: 2 CFR 200; procurement standards at 2 CFR 200 (D)—Procurement Standards; 2 CFR 1207.317 and 2 CFR 200.401; compliance with Federal civil rights laws and regulations; disadvantaged business enterprises requirements; debarment and suspension requirements; drug-free workplace requirements; FRA's and OMB's Assurances and Certifications; ADA; safety requirements; NEPA; EJ requirements; and compliance with 49 U.S.C. 24905(c)(2) for the duration of NEC Projects. Unless otherwise stated in statutory or legislative authority, or appropriations language, all financial assistance awards follow the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards at 2 CFR 200 and 2 CFR 1201.

Assistance under this NOFO is subject to the grant conditions in 49 U.S.C. 22905, including protective arrangements that are equivalent to the protective arrangements established under section 504 of the Railroad Revitalization and Regulatory Reform Act of 1976 (45 U.S.C. 836) with respect to employees affected by actions taken in connection with the project to be financed in whole or in part by grants subject to 49 U.S.C. 22905, the provision deeming operators rail carriers and employers for certain purposes, and grantee agreements with railroad right-of-way owners for projects using railroad rights-of-way (see D.2.b.ii).[14]

Grantees must comply with applicable appropriations act requirements and all relevant requirements of 2 CFR 200. Rights to intangible property under grants awarded under this NOFO are governed in accordance with 2 CFR 200.315. See an example of standard terms and conditions for FRA grant awards at *https://railroads.fra.dot.gov/elibrary/award-administration-and-grant-conditions.* This template is subject to revision.

The FSP–NEC NOFO will be implemented, as appropriate and consistent with law, in alignment with the priorities in Executive Order 14052, *Implementation of the Infrastructure Investment and Jobs Act* (86 FR 64355), which are to invest efficiently and equitably, promote the competitiveness of the U.S. economy, improve job opportunities by focusing on high labor standards, strengthen infrastructure resilience to all hazards including climate change, and to effectively coordinate with State, local, Tribal, and territorial government partners.

a. *Climate Change, Sustainability, and Environmental Justice.* Projects that have not sufficiently considered climate change and sustainability in their planning, as determined by FRA, will be required to do so before receiving funds for construction, consistent with Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad* (86 FR 7619). In the grant agreement, recipients will be expected to describe activities they have taken, or will take, prior to obligation of construction funds that addresses climate change and EJ. Activities that address climate change include, but are not limited to, demonstrating: the project will result in significant greenhouse gas emissions reductions; the project supports emissions reductions goals in a Local/Regional/State plan; and the project primarily focuses on funding for state of good repair and clean transportation options, including public transportation, walking, biking, and micro-mobility. Activities that address EJ include, but are not limited to: basing project design on the results of a proven EJ screening tool (developed by another Federal agency such as the EPA, a State agency, etc.); conducting enhanced, targeted outreach to EJ communities; considering EJ in alternatives analysis and final project design; and supporting a modal shift in freight or passenger movement to reduce emissions or reduce induced travel demand.

b. *Racial Equity and Barriers to Opportunity.* Projects must consider and address equity and barriers to opportunity in their planning, as determined by FRA, and as a condition of receiving construction funds, consistent with Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* (86 FR 7009). The grant agreement should include the grantee's description of activities they have taken, or will take, prior to obligation of construction funds that addresses equity and barriers to opportunity. These activities may include, but are not limited to: completing an equity impact analysis for the project; adopting an equity and inclusion program/plan; conducting meaningful public engagement to ensure underserved communities are provided

[14] FRA has posted final guidance to grantees on implementing protective arrangements at to assist grantees implementing the protective arrangements; and answers to frequently asked questions intended to assist grantees subject to the requirements of 49 U.S.C. 22905(c)(1) at *https://railroads.dot.gov/elibrary/frequently-asked-questions-about-rail-improvement-grant-conditions-under-49-usc-ss-22905c1.*

an opportunity to be involved in the planning process; including investments that either redress past barriers to opportunity or that proactively create new connections and opportunities for underserved communities; hiring from local communities; improving access to or providing economic growth opportunities for underserved, overburdened, or rural communities; or addressing historic or current inequitable air pollution or other environmental burdens and impacts.

c. *Employment Opportunities.* In addition to prioritizing projects that address climate change, proactively address racial equity, and reduce barriers to opportunity, FRA intends to use the FSP–NEC NOFO to support the creation of good-paying jobs with the free and fair choice to join a union and the incorporation of strong labor standards and training and placement programs, especially registered apprenticeships and local hire agreements, in project planning and development. To the extent that applicants have not sufficiently considered job quality and labor rights in their planning, as determined by the Department of Labor, the applicants will be required to do so before receiving funds for construction, consistent with Executive Order 14025, *Worker Organizing and Empowerment* (86 FR 22829), and Executive Order 14052, *Implementation of the Infrastructure Investment and Jobs Act* (86 FR 64335). Specifically, the project planning activities and project delivery actions must support: (a) strong labor standards and the free and fair choice to join a union,[15] including project labor agreements, local hire agreements,[16] distribution of workplace rights notices, and use of an appropriately trained workforce; (b) support of high-quality workforce development programs, including registered apprenticeship, labor-management training programs, and supportive services to help train, place, and retain people in good-paying jobs and apprenticeships; and (c) comprehensive planning and policies to promote hiring and inclusion for all groups of workers, including through the use of local and economic hiring preferences, linkage agreements with workforce programs that serve these underrepresented groups, and proactive plans to prevent harassment.

The Office of Federal Contract Compliance Programs (OFCCP) is charged with protecting America's workers by enforcing equal employment opportunity and affirmative action obligations of employers that do business with the federal government. OFCCP enforces Executive Order 11246, Section 503 of the Rehabilitation Act of 1973, and the Vietnam Era Veterans' Readjustment Assistance Act of 1974. Together these legal authorities make it unlawful for federal contractors and subcontractors to discriminate in employment because of race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or status as a protected veteran. Consistent with E.O. 11246, *Equal Employment Opportunity* (30 FR 12319, and as amended), all Federally assisted contractors are required to make good faith efforts to meet the goals of 6.9 percent of construction project hours being performed by women, in addition to goals that vary based on geography for construction work hours and for work being performed by people of color. Recipients of Federal transportation funding will be required to comply fully with Title VI of the Civil Rights Act of 1964 and implementing regulations (49 CFR 21), the ADA, Section 504 of the Rehabilitation Act of 1973, and all other civil rights requirements. The Department's and FRA's Office of Civil Rights may provide resources and technical assistance to recipients to ensure full and sustainable compliance with Federal civil rights requirements. The OFCCP has a Mega Construction Project Program through which it engages with project sponsors as early as the design phase to help promote compliance with non-discrimination and affirmative action obligations. Through the program, OFCCP offers contractors and subcontractors extensive compliance assistance, conducts compliance evaluations, and helps to build partnerships between the project sponsor, prime contractor, subcontractors, and relevant stakeholders. OFCCP will identify projects that receive an award under this notice and are required to participate in OFCCP's Mega Construction Project Program from a wide range of federally assisted projects over which OFCCP has jurisdiction and that have a project cost above $35 million. DOT will require project sponsors with costs above $35 million that receive awards under this funding opportunity to partner with OFCCP, if selected by OFCCP, as a condition of their DOT award. Under that partnership, OFCCP will ask these project sponsors to make clear to prime contractors in the pre-bid phase that project sponsor's award terms will require their participation in the Mega Construction Project Program. Additional information on how OFCCP makes their selections for participation in the Mega Construction Project Program is outlined under ''Scheduling'' on the Department of Labor website: *https://www.dol.gov/agencies/ofccp/faqs/construction-compliance.*''

d. *Critical Infrastructure Security and Resilience.* It is the policy of the United States to strengthen the security and resilience of its critical infrastructure against both physical and cyber threats. Each applicant selected for Federal funding under this Notice must demonstrate, prior to signing of the grant agreement, efforts to consider and address physical and cyber security risks relevant to the transportation mode and type and scale of the project. Projects that have not appropriately considered and addressed physical and cyber security and resilience in their planning, design, and project oversight, as determined by the DOT and the Department of Homeland Security, will be required to do so before receiving funds for construction, consistent with *Presidential Policy Directive 21—Critical Infrastructure Security and Resilience and the National Security Presidential Memorandum on Improving Cybersecurity for Critical Infrastructure Control Systems.* Information on cybersecurity performance goals can be found at *https://www.cisa.gov/cpg.'*

e. *Domestic Preference Requirements.* Assistance under this NOFO is subject to the Buy America requirements in 49 U.S.C. 22905(a) and the Build America, Buy America Act, Public Law 117–58, 70901–52. In addition, as expressed in Executive Order 14005, *Ensuring the Future Is Made in All of America by All of America's Workers* (86 FR 7475), it is the policy of the executive branch to maximize, consistent with law, the use of goods, products, and materials produced in, and services offered in, the United States. FRA expects all applicants to comply with that requirement without needing a waiver. However, to obtain a waiver, a recipient must be prepared to demonstrate how they will maximize the use of domestic goods, products, and materials in constructing their project. If an applicant anticipates it may need a waiver, the applicant should indicate the need in its application and submit

[15] Federal funds may not be used to support or oppose union organizing, whether directly or as an offset for other funds.

[16] IIJA div. B section 25019 provides authority to use geographical and economic hiring preferences, including local hire, for construction jobs, subject to any applicable State and local laws, policies, and procedures.

materials necessary for such requests together with its application.

f. *Civil Rights and Title VI.* Applications should demonstrate that the recipient has a plan for compliance with civil rights obligations and nondiscrimination laws, including Title VI of the Civil Rights Act of 1964 and implementing regulations (49 CFR 21), the ADA, and section 504 of the Rehabilitation Act, and accompanying regulations. This may include, as applicable, providing a Title VI plan, community participation plan, and other information about the communities that will be benefited and impacted by the project. The DOT's and FRA's Office of Civil Rights may provide resources and technical assistance to recipients to ensure full and sustainable compliance with Federal civil rights requirements.

3. Reporting

a. Progress Reporting on Grant Activity

Each applicant selected for a grant will be required to comply with all standard FRA reporting requirements, including quarterly progress reports, quarterly Federal financial reports, and interim and final performance reports, as well as all applicable auditing, monitoring and close out requirements. Reports may be submitted electronically. Pursuant to 2 CFR 170.210, non-Federal entities applying under this NOFO must have the necessary processes and systems in place to comply with the reporting requirements should they receive Federal funding.

b. Additional Reporting

Applicants selected for funding are required to comply with all reporting requirements in the standard terms and conditions for FRA grant awards including 2 CFR 180.335 and 2 CFR 180.350.

If the Federal share of any Federal award under this NOFO may include more than $500,000 over the period of performance, applicants are informed of the post award reporting requirements reflected in 2 CFR 200, Appendix XII—Award Term and Condition for Recipient Integrity and Performance Matters.

c. Performance and Program Evaluation

As a condition of grant award, grant recipients may be required to participate in an evaluation undertaken by DOT, or another agency or partner. The evaluation may take different forms such as an implementation assessment across grant recipients, an impact and/or outcomes analysis of all or selected sites within or across grant recipients, or a benefit/cost analysis or assessment of return on investment. The Department may require applicants to collect data elements to aid the evaluation. As a part of the evaluation, as a condition of award, grant recipients must agree to: (1) make records available to the evaluation contractor; (2) provide access to program records, and any other relevant documents to calculate costs and benefits; (3) in the case of an impact analysis, facilitate the access to relevant information as requested; and (4) follow evaluation procedures as specified by the evaluation contractor or DOT staff.

Recipients and subrecipients are also encouraged to incorporate program evaluation, including associated data collection activities from the outset of their program design and implementation, to meaningfully document and measure their progress towards meeting an agency priority goal(s). Title I of the Foundations for Evidence-Based Policymaking Act of 2018, Public Law 115–435 (2019) urges Federal awarding agencies and Federal assistance recipients and subrecipients to use program evaluation as a critical tool to learn, to improve equitable delivery, and to elevate program service and delivery across the program lifecycle. Evaluation means ''an assessment using systematic data collection and analysis of one or more programs, policies, and organizations intended to assess their effectiveness and efficiency.'' (5 U.S.C. 311). Credible program evaluation activities are implemented with relevance and utility, rigor, independence and objectivity, transparency, and ethics (OMB Circular A–11, Part 6, Section 290).

For grant recipients receiving an award, evaluation costs are allowable costs (either as direct or indirect), unless prohibited by statute or regulation, and such costs may include the personnel and equipment needed for data infrastructure and expertise in data analysis, performance, and evaluation. (2 CFR 200).

d. Performance Reporting

Each applicant selected for funding must collect information and report on the project's performance using measures mutually agreed upon by FRA and the grantee to assess progress in achieving strategic goals and objectives. Examples of some rail performance measures are listed in the table below. The applicable measure(s) will depend upon the type of project. Applicants requesting funding for rolling stock must integrate at least one equipment/rolling stock performance measure, consistent with the grantee's application materials and program goals.

Rail measures	Unit measured	Temporal	Primary strategic goal	Description
Slow Order Miles Reduced	Miles	Annual	Economic Strength and Global Competitiveness.	The number of miles per year within the project area that have temporary speed restrictions (''slow orders'') imposed due to track condition. This is an indicator of the overall condition of track. This measure can be used for projects to rehabilitate sections of a rail line since the rehabilitation should eliminate, or at least reduce the slow orders upon project completion.
Number of Passenger Trains.	Count	Annual	Economic Strength and Global Competitiveness.	The number of daily passenger trains between city pairs.
Passenger Counts	Count	Annual	Economic Strength and Global Competitiveness.	Count of the annual passenger boardings and alightings at stations within the project area.
Delay Minutes	Time/Trip	Annual	Economic Strength and Global Competitiveness.	Point-to-point delay minutes reduced between pre-determined station stops within the project area. This measure demonstrates how track improvements and other upgrades improve operations on a rail line. It also helps make sure the railroad is maintaining the line after project completion.

Rail measures	Unit measured	Temporal	Primary strategic goal	Description
Track Miles	Miles	One Time	Economic Strength and Global Competitiveness.	The number of track miles replaced and/or rehabilitated that exist within the project area. This measure can be beneficial for projects building sidings or sections of additional main line track on a railroad.

G. Federal Awarding Agency Contacts

For further information concerning this Notice, please contact the FRA NOFO Support program staff via email at *FRA-NOFO-Support@dot.gov.* If additional assistance is needed, you may contact Mr. Bryan Rodda, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–203, Washington, DC 20590; email: *Bryan.Rodda@dot.gov;* telephone: 202–493–0443.

H. Other Information

All information submitted as part of or in support of any application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If the application includes information the applicant considers to be a trade secret or confidential commercial or financial information, the applicant should do the following: (1) Note on the front cover that the submission ''Contains Confidential Business Information (CBI)''; (2) mark each affected page ''CBI''; and (3) highlight or otherwise denote the CBI portions.

The DOT regulations implementing the Freedom of Information Act (FOIA) are found at 49 CFR 7 (C)—Availability of Reasonably Described Records under the Freedom of Information Act which sets forth rules for FRA to make requested materials, information, and records publicly available under FOIA. Unless prohibited by law and to the extent permitted under the FOIA, contents of application and proposals submitted by successful applicants may be released in response to FOIA requests. In addition, following the completion of the selection process and announcement of awards, FRA may publish a list of all applications received along with the names of the applicant organizations and funding amounts requested. Except for information withheld under the previous paragraph, FRA may also make application narratives publicly available or share application information within DOT or with other Federal agencies if FRA determines that sharing is relevant to the respective program's objectives.

Issued in Washington, DC.

Jennifer Mitchell,

Deputy Administrator.

[FR Doc. 2022–28034 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0059; Notice 1]

Daimler Trucks North America, LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Daimler Trucks North America, LLC, (DTNA) has determined that certain model year (MY) 2022–2023 Freightliner (FCCC) EconicSD do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 106, *Brake Hoses.* DTNA filed a noncompliance report dated May 12, 2022. DTNA subsequently petitioned NHTSA on June 8, 2022, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces receipt of DTNA's petition.

DATES: Send comments on or before January 26, 2023.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and be submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal Holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the docket. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000, (65 FR 19477–78).

FOR FURTHER INFORMATION CONTACT: Manuel Maldonado, Safety Compliance Engineer, NHTSA, Office of Vehicle Safety Compliance, (202) 366–8731.

SUPPLEMENTARY INFORMATION:

I. Overview

DTNA has determined that certain MY 2022–2023 Freightliner (FCCC) EconicSD do not fully comply with paragraphs S11.3.18 and S11.3.19 of FMVSS No. 106, *Brake Hoses* (49 CFR 571.106). DTNA filed a noncompliance report dated May 12, 2022, pursuant to 49 CFR 573, *Defect and Noncompliance Responsibility and Reports.* DTNA subsequently petitioned NHTSA on June 8, 2022, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 40 U.S.C. 30118 and 49 U.S.C. 30120, *Exemption for Inconsequential Defect or Noncompliance.*

This notice of receipt of DTNA's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any Agency decision or other exercise of judgment concerning the merits of the petition.

II. Vehicles and Equipment Involved

Approximately 149 MY 2022–2023 Freightliner (FCCC) EconicSD, manufactured between June 24, 2019, and March 9, 2022, are potentially involved. The part numbers of the fittings involved are A 000 990 40 78 and A 000 990 43 78.

III. Noncompliance

DTNA explains that the noncompliance is that certain fittings used in the subject vehicle's air brake system failed to pass the tensile strength test under boiling conditions and tensile strength test under thermal conditioning, and therefore, do not comply with paragraphs S11.3.18 and S11.3.19 and Table VIII of FMVSS No. 106. The subject vehicles are equipped with an air brake system containing tubing that has a nominal outside diameter (OD) of 8 mm and do not meet the conditioned tensile load 75 lbf as required by Table VIII of FMVSS No. 106.

IV. Rule Requirements

Paragraphs S11.3.18 and S11.3.19 of FMVSS No. 106 include the requirements relevant to this petition. S11.3.18 requires that a plastic air brake tubing assembly, when subjected to a tensile pull test, must either elongate 50 percent or withstand the conditioned tensile load in Table VIII of FMVSS No. 106 without separation from its end fittings, with one end of the assembly conditioned in boiling water for 5 minutes. S11.3.19 requires that a plastic air brake tubing assembly, when subjected to a tensile pull test, must either elongate 50 percent or withstand the conditioned tensile load in Table VIII without separation from its end fittings after the assembly has been subjected to four cycles of conditioning in air at minus 40 degrees Fahrenheit (minus 40 degrees Celsius) for thirty minutes, normalizing at room temperature, conditioning in boiling water for 15 minutes, and normalizing at room temperature.

V. Summary of DTNA's Petition

The following views and arguments presented in this section, ''V. Summary of DTNA's Petition,'' are the views and arguments provided by DTNA. They have not been evaluated by the Agency and do not reflect the views of the Agency.

DTNA describes the subject noncompliance and states that the noncompliance is inconsequential as it relates to motor vehicle safety. DTNA explains that the subject noncompliance occurred because DTNA carried over a European Econic vehicle fitting into the U.S. market that had been believed to be compliant to FMVSS No. 106. DTNA later discovered it was not certified to paragraphs S11.3.18 and S11.3.19 of FMVSS No. 106. DTNA says that the noncompliant fittings ''are used only in locations protected from stresses and thermal/boiling conditions.'' Therefore, DTNA believes that the subject noncompliance should be deemed inconsequential to motor vehicle safety because the noncompliant fittings are protected from the stresses that are tested by paragraphs S11.3.18 and S11.3.19 of FMVSS No. 106.

DTNA states that the noncompliant fittings have been used for 9 years in the European market and 3 years in the U.S. and Canadian markets, and ''there has been no evidence of airline separations.'' DTNA investigated claims related to tensile loads on the noncompliant fittings that were used in the subject vehicles across all of the vehicles with the same fitting that were sold in Europe, the United States, and Canada, and found no evidence of problems.

DTNA describes the location of the noncompliant fitting in the subject vehicle and provides photos to show that the noncompliant fittings ''are mounted with protections and stress relief, such that there are none of the tensile loads against which the FMVSS [No.] 106 provision was intended to protect.'' Due to the location of the fittings, DTNA contends that they ''would not be subjected to any loads'' and the area ''is expected to be free from debris, boiling water, abnormally high temperatures, and so forth, such that the integrity of the fittings would not be affected.'' Further, DTNA states the noncompliant fittings have never failed and DTNA is not aware of ''any scenarios which would cause the air fittings to separate from the connection points.''

DTNA says that it tested a sample of the tubing configuration used in the subject vehicles and found that the tubing failed during all four pull strength tests at an average of 37.5 lbf for tensile load strength, which is 50 percent less than what is required by S12.19 of FMVSS No. 106. However, DTNA stated its belief that the tubing would not be subjected to tensile forces as high as the 75 pounds required by FMVSS No. 106 due to the location of the air brake system used in the subject vehicles, as described above.

DTNA claims that NHTSA precedent supports granting DTNA's petition for the subject noncompliance. DTNA refers to the granting of a petition submitted by Coupled Products, Inc.[1], in which brake hose assemblies it produced did not comply with the tensile strength requirement provided in S5.3.4 of FMVSS No. 106 (a hydraulic brake hose assembly is required to withstand a pull of 325 pounds without separations of the hose from its end fittings during a slow pull test, and a pull of 370 pounds during a fast pull test) and the water absorption and tensile strength requirement provided in S5.3.6 (a hydraulic brake hose assembly, after immersion in water for 70 hours, is required to withstand a pull of 325 pounds without separation of the hose from its end fittings during a slow pull test, and a pull of 370 pounds during a fast pull test). DTNA believes that, like the noncompliance that Coupled Products, Inc., described, the noncompliant fittings used in the subject vehicles are also ''restrained within assemblies under the cab body and protected under the dash,'' therefore, DTNA contends that there are no forces acting upon the noncompliant fittings.

DTNA concludes by again contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, be granted.

DTNA's complete petition and supporting documents are available by logging onto the Federal Docket

[1] Coupled Products, Inc., Grant of Petition for Decision of Inconsequential Noncompliance; 70 FR 35774 (June 21, 2005).

Management System (FDMS) website at: *https://www.regulations.gov* and by following the online search instructions to locate the docket number as listed in the title of this notice.

VI. Additional Information

On July 6, 2022, NHTSA contacted DTNA for clarification on certain parts of its petition. DTNA provided the name of the fabricating manufacturer for the hose assemblies, Arco, and provided the intended OD of the hose assemblies, 8 mm. DTNA also clarified the statements describing the testing of the sample tubing configuration. DTNA provided the test results and found that the average tensile load at which the noncompliant component failed was 37.5 lbf.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject vehicles and equipment that DTNA no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant brake hoses and equipment under their control after DTNA notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2022–28062 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket Nos. NHTSA–2021–0056, NHTSA–2021–0057; Notice 1]

Vee Rubber Corporation Ltd. and American Honda Motor Co., Inc., Receipt of Petitions for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petitions.

SUMMARY: Vee Rubber Corporation Ltd. (VRC) and American Honda Motor Co., Inc., (Honda) have determined that certain Vee Rubber VRM133 motorcycle tires sold as replacement equipment and as original equipment for installation on certain model year (MY) 2019–2021 Honda Monkey motorcycles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 Kilograms (10,000 Pounds), Specialty Tires, and Tires for Motorcycles.* VRC filed a noncompliance report dated June 7, 2021, and Honda filed a noncompliance report dated June 22, 2021. Subsequently, VRC petitioned NHTSA on June 22, 2021, and Honda petitioned NHTSA on July 14, 2021, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces receipt of VRC and Honda's petitions.

DATES: Send comments on or before January 26, 2023.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on these petitions. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petitions are granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the docket. The docket ID numbers for these petitions are shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 194772012;78).

FOR FURTHER INFORMATION CONTACT: Jayton Lindley, General Engineer, NHTSA, Office of Vehicle Safety Compliance, (325) 655–0547.

SUPPLEMENTARY INFORMATION:

I. Overview

VRC and Honda have determined that certain Vee Rubber VRM133 motorcycle tires sold as replacement equipment and as original equipment for installation on certain 2019–2021 Honda Monkey motorcycles do not fully comply with the requirements of paragraph S6.5(b) of FMVSS No. 119, *New Pneumatic Tires for Motor Vehicles with a GVWR of More Than 4,536 Kilograms (10,000 Pounds), Specialty Tires, and Tires for Motorcycles* (49 CFR 571.119).

VRC filed a noncompliance report dated June 7, 2021, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* VRC subsequently petitioned NHTSA on June 22, 2021, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

Honda filed a noncompliance report dated June 22, 2021, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Honda subsequently petitioned NHTSA on July 14, 2021, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

This notice of receipt of VRC and Honda's petitions is published under 49 U.S.C. 30118 and 30120 and does not represent any Agency decision or other exercise of judgment concerning the merits of the petitions.

II. Tires Involved

Approximately 29,018 Vee Rubber VRM133 motorcycle tires sizes 120/80–12 and 130/80–12, sold as replacement equipment and to Honda for installation in certain Honda motorcycles, and manufactured between March 5, 2018, and May 27, 2021, are potentially involved.

The subject tires were installed as original equipment on approximately 13,328 MY 2019–2021 Honda Monkey motorcycles manufactured between July 4, 2018, and April 2, 2021, and therefore these vehicles are also potentially involved.

III. Noncompliance

VRC and Honda explain that the noncompliance is that the subject tires contain extra markings between the manufacturer's code and production week mark within the tire identification number (TIN), and, therefore, do not comply with the requirements specified in paragraph S6.5(b) of FMVSS No. 119. Specifically, the tires included an extra grouping of characters, beginning with the letter ''V'' followed by numbers between the second and third grouping of characters. For example, the tires were marked ''DOT 15A BCN133 Vxxxxxx xxxx'' or ''DOT 15A BBN133 Vxxxxxx xxxx'' when they should have been marked ''DOT 15A BCN133 xxxx'' or ''DOT 15A BBN133 xxxx,'' with ''x'' representing the number present on a specific tire.

IV. Rule Requirements

Paragraph S6.5(b) of FMVSS No. 119 includes the requirements relevant to these petitions. S6.5(b) provides that the TIN must meet the requirements as stated in 49 CFR 574 and may be marked on only one sidewall. 49 CFR 574.5(a) requires, in relevant part, that each new tire manufacturer must conspicuously label on one sidewall of each tire it manufactures, by permanently molding into or onto the sidewall, a TIN consisting of 13 symbols that contains the plant code, manufacturer's code, and date code, as described in paragraphs (b)(1) through (b)(3) of 49 CFR 574.5.

V. Summary of VRC and Honda's Petitions

The following views and arguments presented in this section, ''V. Summary of VRC and Honda's Petitions,'' are the views and arguments provided by VRC and Honda. They have not been evaluated by the Agency and do not reflect the views of the Agency. VRC and Honda describe the subject noncompliance and contend that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of their petitions, VRC and Honda submitted the following reasoning:

VRC claims that the subject tires meet the performance requirements of FMVSS No. 119 and, therefore, the ''markings have no impact on the operational performance of the tires or on the safety of motorcycles on which these tires are installed.'' VRC also claims that the subject tires contain ''a complete and identifiable TIN which is accessible while mounted'' and that in the event of a recall, a consumer would have access to all the necessary information required to determine whether their tires are subject to a recall.

In Honda's petition, they state that they support VRC's petition and believe that the extra markings on the tires do not pose a safety risk to riders or affect the performance of the subject motorcycle tires. Honda added that the subject tires are both identifiable and traceable since the extra markings ''do not alter or remove any required identifying characters of the TIN.''

The petitioners referred to the following inconsequential noncompliance petitions granted by NHTSA that they believe support the granting of their petitions for the subject noncompliance:

- Michelin North America, Inc., Grant of Petition for Decision of Inconsequential Noncompliance; 85 FR 37495, June 22, 2020.
- Bridgestone Firestone North America Tire, LLC, Grant of Petition for Decision of Inconsequential Noncompliance; 71 FR 4396, January 26, 2006.
- Cooper Tire & Rubber Company, Grant of Petition for Decision of Inconsequential Noncompliance; 71 FR 4396, January 26, 2006.
- Cooper Tire & Rubber Company, Grant of Petition for Decision of Inconsequential Noncompliance; 82 FR 17075, April 7, 2017.
- Nitto Tire USA., Inc., Grant of Petition for Decision of Inconsequential Noncompliance; 81 FR 17764, March 30, 2016.
- Hankook Tire America, Grant of Petition for Decision of Inconsequential Noncompliance; 79 FR 30688, May 28, 2014.

The petitioners state that they are not aware of any customer claims, complaints, injuries, incidents, or field reports associated with the extra markings in the TIN on the affected tires.

VRC states that they have already corrected the error at its plant so that the TIN on all new Model VRM133 tires in the affected sizes will be marked according to S6.5(b) of FMVSS No. 119. VRC also states that they have recovered all affected tires in possession of United States distributors or retailers that have not yet reached end-users.

The petitioners conclude their petitions by contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety and that their petitions to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on these petitions only applies to the subject tires and vehicles that the petitioners no longer controlled at the time it determined that the noncompliance existed. However, any decision on these petitions does not relieve tire and vehicle distributors and dealers of the prohibitions on the sale,

offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires and vehicles under their control after VRC and Honda notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2022–28061 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0080]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Request for Comment; Child Passenger Safety Perceptions and Practices in Ridesharing and Autonomous Vehicles

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for approval of a new information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden. This ICR is for a new collection of information for which NHTSA intends to seek OMB approval on Child Passenger Safety Perceptions and Practices in Ridesharing and Autonomous Vehicles. A **Federal Register** notice with a 60-day comment period soliciting comments on the following information collection was published on October 17, 2022. NHTSA received two sets of comments from three organizations, which we address below.

DATES: Comments must be submitted on or before January 26, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection, select ''Currently under Review—Open for Public Comment'' or use the search function.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Kathy Sifrit, Ph.D., Office of Behavioral Safety Research (NPD–320), (202) 366–9982, National Highway Traffic Safety Administration, W46–472, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted OMB.

Title: Child Passenger Safety Perceptions and Practices in Ridesharing and Autonomous Vehicles.

OMB Control Number: New.

Form Numbers: NHTSA Forms 1687, 1688, 1689, and 1690.

Type of Request: Approval of a new information collection.

Type of Review Requested: Regular.

Length of Approval Requested: Three years from date of approval.

Summary of the Collection of Information: The National Highway Traffic Safety Administration (NHTSA) of the U.S. Department of Transportation is seeking approval for a one-time voluntary information collection from 24 caregivers of children 8 years old or younger and 12 licensed drivers of rideshare vehicles. The purpose of the collection is to describe child passenger safety (CPS) attitudes and behaviors from caregivers and rideshare drivers. A NHTSA contractor expects to provide screening questionnaires to 200 potential participants to determine their eligibility for the focus group study and to collect contact information for scheduling with a potential burden of 15 minutes per respondent or 50 hours. From the 200 potential participants, the contractor will contact and enroll up to 36 participants in the study. Six 90-minute focus groups will be conducted, each with six participants. Including the five minutes for participants to complete informed consent, the burden per focus group participant is 95 minutes or 57 hours. The total expected burden for screening, scheduling, and participating in the focus groups is 107 hours. A trained moderator will conduct separate virtual focus groups for caregivers/parents of at least one child 8 years old or younger who frequently use rideshare vehicles to transport children (two groups) and those who infrequently transport children in rideshare vehicles (two groups) as well as for rideshare drivers who frequently have child passengers 8 years old or younger (one group) and those who infrequently have child passengers (one group). The contractor will collect participants' attitudes and self-reported behaviors from the focus groups. NHTSA's contractor received Institutional Review Board (IRB) approval to conduct the focus groups. NHTSA will use the information to produce a technical report containing descriptive and qualitative assessments of caregivers/parents' and rideshare drivers' attitudes and behaviors related to CPS in rideshare vehicles. NHTSA will make the technical report available to a variety of audiences interested in improving highway safety through the agency website and the National Transportation Library. This collection will inform the development of behavioral safety countermeasures, particularly in the areas of communications and training related to CPS in rideshare vehicles and potentially future vehicles with Automated Driving Systems.

Description of the Need for the Information and Proposed Use of the Information: NHTSA has estimated that using a car seat reduces the risk of fatal injury for infants (under 1 year old) by 71 percent for passenger cars and by 58 percent for light trucks such as pickups, SUVs, and minivans. For toddlers (1 to 4 years old), the corresponding reductions are 54 percent and 59 percent. [1] However, children are not always restrained appropriately. In 2020 there were 181 passenger vehicle occupant fatalities among children under 4 years old, and 31 percent were unrestrained (based on known restraint use). In the 4-to-7 age group, there were 207 fatalities; 43 percent were unrestrained (based on known restraint use).[2]

[1] Kahane, C. J. (2015, January). *Lives saved by vehicle safety technologies and associated Federal Motor Vehicle Safety Standards, 1960 to 2012—Passenger cars and LTVs—With reviews of 26 FMVSS and the effectiveness of their associated safety technologies in reducing fatalities, injuries, and crashes* (Report No. DOT HS 812 069). National Highway Traffic Safety Administration. *https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812069*

[2] National Center for Statistics and Analysis. (2022, July). *Occupant protection in passenger vehicles: 2020 data* (Traffic Safety Facts. Report No.

The use of ridesharing services has increased dramatically over the past few years. In 2018, 36 percent of U.S. adults used ridesharing services, such as Uber and Lyft. This percentage is more than twice the share of the population who used ridesharing apps in 2015.[3] As the use of ridesharing vehicles increases, concerns regarding how children are being transported in these vehicles are emerging. However, limited research has been conducted on CRS use in ridesharing vehicles. A study conducted by Prince, et al. showed lower rates of CRS use and higher rates of injuries in crashes involving taxis in New York City.[4] In an online national survey of parents with children under eight, 59 percent reported that they transported their children differently when traveling in rideshare vehicles compared with private vehicles.[5] Of those, 37 percent reported holding the child on their lap and 25 percent allowed the child to ride without a CRS. Several online and in-person surveys with parents and caregivers point to specific circumstances in which non-use of CRS is perceived as more acceptable, including riding in a rideshare or taxi; traveling while on vacation, carpooling, when traveling short distances; and finding there is no CRS available.[6] [7] [8]

There also is a lack of research on best practice approaches for promoting child safety in rideshare vehicles, and regulatory inconsistencies (*e.g.,* types of vehicles covered under restraint laws, severity of fines for violations of the law, age of child covered by child restraint laws, etc.) only contribute to the confusion on the part of caregivers and rideshare drivers. A better understanding of caregiver and rideshare driver behaviors and attitudes related to restraint use in rideshare services is needed to inform the development of public policy, regulations, enforcement measures, and educational campaigns.

60-Day Notice: A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on October 17, 2022 (87 FR 62922). Two sets of comments were submitted by three organizations: one comment was submitted by Safe Kids Worldwide and Safe Kids in Automated Vehicle Alliance (SKAVA), and the other comment was submitted by the Texas Department of Transportation (TxDOT). Safe Kids Worldwide, SKAVA, and the TxDOT were supportive of the agency's efforts to understand the behavior and attitudes of caregivers and rideshare drivers regarding child passenger safety (CPS) in rideshare vehicles. Safe Kids Worldwide and SKAVA noted that this research will help inform solutions to inconsistencies with CPS in rideshare vehicles. TxDOT recommended some changes in project design to enhance the quality, utility, and clarity of the information to be collected. We appreciate the comments from Safe Kids Worldwide, SKAVA, and TxDOT and thank them for thoughtfully considering the described program.

The TxDOT raised concerns about the study design. They expressed concern that the number of participants in the focus groups would not be representative of the population and recommended increasing the sample size. The data collection plan includes enrolling 36 participants (24 caregivers and 12 rideshare drivers) for the focus groups. While we recognize that this may seem to be a small sample size, this number is in line with qualitative research methods guidelines suggesting that 4–8 participants are enough to reach saturation in focus group research.[9] Additionally, TxDOT noted the current study would be useful to examine attitudes and behaviors related to advanced driver assistance systems (ADAS) available in the market and used in some rideshare vehicles, and whether the existence of ADAS impacts choice and use of rideshare vehicles. We agree that examining attitudes and behaviors related to ADAS in rideshare vehicles is important; however, this line of questioning is unrelated to understanding CPS in rideshare vehicles and is beyond the scope of this study.

Affected Public: Parents of children 8 years old or younger and adult licensed drivers of ridesharing vehicles.

Estimated Number of Respondents: 200 potential participants with 36 participating in focus groups.

Frequency: This study is a one-time information collection, and there will be no recurrence.

Number of Responses: Each respondent responds to each form only once.

Estimated Total Annual Burden Hours: The total estimated burden with this collection is 107 hours. NHTSA estimates that up to 200 potential respondents will need to be screened for eligibility by completing a 10-minute screening questionnaire before finding 36 people to participate in the focus groups. The contractor will contact the eligible participants to determine whether they are still interested and if so, to schedule a focus group for an additional potential burden of five minutes. As such, screening and scheduling may take up to 15 minutes per potential participant. The goal is to schedule 36 participants for six focus groups (four caregiver groups and two driver groups).

Each focus group is estimated to last 90 minutes. Including informed consent, NHTSA estimates the burden as 95 minutes per participant. During the focus group, participants will discuss their experiences in traveling with children in rideshare vehicles, behavior with respect to using seat belts or CRSs when travelling in personal vehicles and rideshare vehicles, opinions regarding CPS in rideshare vehicles, etc. Assuming a 10-minute completion time for the recruitment screener questionnaire, 5 minutes for contacting and scheduling potential participants for the focus group sessions, 5 minutes for informed consent for participants, and 90 minutes for participating in the focus groups the total hour burden 107 hours. The calculation of the total estimated burden is shown in Table 1 below.

DOT HS 813 326). National Highway Traffic Safety Administration. *https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/813326*

[3] Pew Research Center (2019, January 4). *More Americans are using ride-hailing apps. https://www.pewresearch.org/fact-tank/2019/01/04/more-americans-are-using-ride-hailing-apps/.*

[4] Prince, P., Hines, L. M., Bauer, M. J., Liu, C., Luo, J., Garnett, M., & Pressley, J. C. (2019). Pediatric Restraint Use and Injury in New York City Taxis Compared with Other Passenger Vehicles. *Transportation Research Record, 2673*(7), 541–549. *https://doi.org/10.1177/0361198119843091.*

[5] Owens, J. M., Womack, K. T., & Barowski, L. (2019, September). *Factors Surrounding Child Seat Usage in Rideshare Services* (Technical Report No. 01–005). Safety through Disruption (Safe-D) University Transportation Center. *https://rosap.ntl.bts.gov/view/dot/63050.*

[6] Levi, S., Lee, H., Ren, W., Polson, A., & McCloskey, S. (2020, December). Awareness and availability of child passenger safety information resources (Report No. DOT HS 813 035). National Highway Traffic Safety Administration. *https://rosap.ntl.bts.gov/view/dot/54283.*

[7] McDonald, C., Kennedy, E., Fleisher, L., & Zonfrillo, M. (2018). Situational Use of Child Restraint Systems and Carpooling Behaviors in Parents and Caregivers. *International Journal of Environmental Research and Public Health, 15*(8), 1788. *https://doi.org/10.3390/ijerph15081788.*

[8] Niu, L., Gao, Y. M., Tian, Y., & Pan, S. M. (2019). Safety awareness and use of child safety seats among parents after the legislation in Shanghai. *Chinese journal of traumatology = Zhonghua chuang shang za zhi, 22*(2), 85–87. *https://doi.org/10.1016/j.cjtee.2018.08.005.*

[9] Hennink, M. & Kaiser, B. N. (2022). Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Social Science & Medicine, 292.* 1–10. *https://doi.org/10.1016/j.socscimed.2021.114523.*

TABLE 1—ESTIMATED BURDEN HOURS BY FORM

Form No.	Form name and description	Respondents	Time per respondent (minutes)	Total time (hours)
1687	Screener and Follow-Scheduling	200	15	50
1688	Informed Consent (Caregivers)	24	5	2
1689	Informed Consent (Drivers)	12	5	1
1690	Focus Group Participation	36	90	54
Total ...	.....	.....	.....	107

Estimated Total Annual Burden Cost: NHTSA estimates that there are no costs to respondents beyond the time spent participating in the study.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29A.

Nanda Narayanan Srinivasan,

Associate Administrator, Research and Program Development.

[FR Doc. 2022–28132 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2018–0190]

Aviation Consumer Protection Advisory Committee; Notice of Public Meeting

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of public meeting.

SUMMARY: This Notice announces a one-day public meeting of the Aviation Consumer Protection Advisory Committee (ACPAC), to be held virtually. The ACPAC will deliberate on the Department's notice of proposed rulemaking (NPRM) on Enhancing Transparency of Airline Ancillary Service Fees; and will vote on recommendations regarding the Department's NPRM on Airline Ticket Refunds and Consumer Protections.

DATES: The virtual meeting will be held on, January 12, 2023, from 10:00 a.m. to 5:30 p.m. Eastern Standard Time. The meeting is open to the public, subject to any technical and/or capacity limitations. Requests to attend the meeting must be submitted to *https://usdot.zoomgov.com/webinar/register/WN_Eoow5BMfRTum03htlms2bQ.* We encourage interested parties to register by January 5, 2023. Communication Access Real-time Translation (CART) and sign language interpretation will be provided during the meeting. Requests for additional accommodations because of a disability must be received at *ACPAC@dot.gov* by January 5, 2023.

ADDRESSES: The virtual meeting will be open to the public and held via the Zoom Webinar Platform. Virtual attendance information will be provided upon registration. An agenda will be available on the Department's Office of Aviation Consumer Protection website at *https://www.transportation.gov/airconsumer/ACPAC* in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: To register and attend this virtual meeting, please use the link: *https://usdot.zoomgov.com/webinar/register/WN_Eoow5BMfRTum03htlms2bQ.*

Attendance is open to the public subject to any technical and/or capacity limitations. For further information, please contact Cristina Draguta, Attorney-Advisor, by email at *Cristina.Draguta@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The ACPAC evaluates the Department of Transportation's aviation consumer protection programs, provides recommendations to the Secretary for improving them and recommends any additional consumer protections that may be needed.

During the June 28, 2022, meeting of the ACPAC, the subject of transparency of airline ancillary service fees was considered as members heard presentations about previous Department actions in this area and the perspectives of various stakeholders. On September 26, 2022, the Department announced the Enhancing Transparency of Airline Ancillary Service Fees NPRM (RIN 2105–AF10) (Ancillary Fees Transparency NPRM) and made the rulemaking available on its website and regulations.gov. On December 8, 2022, the ACPAC continued the discussion on this topic, heard from the public, and considered the proposals in the Department's NPRM. The Department is now scheduling a meeting to provide the ACPAC further opportunity to discuss, deliberate, and decide on recommendations, if any, to the Department regarding the Department's Ancillary Fees Transparency NPRM.

Also, on December 9, 2022, the ACPAC deliberated on the Department's Airline Ticket Refunds and Consumer Protections NPRM and decided to vote on the recommendations to the Department once the Ticket Refunds NPRM comment period closes on December 16, 2022. As such, at this meeting, the ACPAC will also vote on recommendations regarding the Department's Airline Ticket Refunds and Consumer Protections NPRM. More information regarding prior meetings, including recordings of meetings, can be found on the ACPAC web pages available here: *https://www.transportation.gov/airconsumer/ACPAC.*

II. Agenda

During the January 12, 2023, meeting, the ACPAC will deliberate and decide on recommendations, if any, to the Department regarding airline ancillary service fee transparency. Pursuant to 49 U.S.C. 41712, which prohibits U.S. air carriers, foreign air carriers, and ticket agents from engaging in unfair or deceptive practices in the sale of air transportation, the Department's Ancillary Fees Transparency NPRM

proposes to require carriers and ticket agents to clearly disclose baggage fees, change fees, and cancellation fees to consumers whenever fare and schedule information is provided to consumers for flights to, within, and from the United States. The Ancillary Fees Transparency NPRM also proposes to require these entities to clearly disclose, whenever fare and schedule information is provided, the fees for adjacent seating, if any, to consumers traveling with young children on flights to, within, and from the United States, and make these fees transactable. The Department is proposing that all of these disclosures be provided on a passenger-specific or itinerary-specific basis. The Department is also proposing to require that carriers provide useable, current, and accurate information regarding these fees to ticket agents that sell or display the carrier's fare and schedule information.

In addition, the ACPAC will vote on the recommendations to the Department made by the Members during December 8, 2022, meeting regarding the Department's Airline Ticket Refunds and Consumer Protections NPRM. More information regarding prior meetings, including recordings of meetings, can be found on the ACPAC web pages available here: *https://www.transportation.gov/airconsumer/ACPAC.*

III. Public Participation

The January 12, 2023, the meeting will begin at 10:00 a.m. EST, and the Committee members will deliberate and decide on recommendations, if any, to make to the Department on Ancillary Fees Transparency NPRM. The ACPAC will also vote on recommendations regarding the Department's NPRM on Airline Ticket Refunds and Consumer Protections. At the January 12, 2023, ACPAC meeting, the members of the public will be able to observe deliberations and voting by ACPAC on the topics mentioned above. However, there will not be an opportunity to make oral comments. Members of the public may submit written comments for the ACPAC consideration electronically to the ACPAC Docket (DOT–OST–2018–0190) any time before the meeting.

IV. Viewing Documents

Documents associated with the ACPAC maybe be accessed in the ACPAC Docket (DOT–OST–2018–0190). Documents associated with the NPRM on Enhancing Transparency of Airline Ancillary Service Fees may be accessed in the rulemaking Docket (DOT–OST–2022–0109). Documents associated with the NPRM on Airline Ticket Refunds and Consumer Protections may be accessed in the rulemaking Docket (DOT–OST–2022–0089). Dockets may be accessed at *https://www.regulations.gov.* After entering the relevant docket number click the link to ''Open Docket Folder'' and choose the document to review.

Signed in Washington, DC.

John E. Putnam,

General Counsel.

[FR Doc. 2022–28099 Filed 12–23–22; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the name of a person whose property and interests in property have been unblocked.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION: Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On December 21, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person are unblocked and the person is removed from the SDN List under the relevant sanctions authority listed below.

Individual:

1. CASTILLO CASTILLO, Orlando Jose (a.k.a. CASTILLO, Orlando), Residencial Bolonia, Canal 2 1 Cuadra Al Sur 3 C Al Oeste, Managua, Nicaragua; DOB 02 Sep 1943; POB Esteli, Nicaragua; nationality Nicaragua; Gender Male; Passport C01713933 (Nicaragua) issued 24 Jul 2014 expires 24 Jul 2024; National ID No. 1610209430002G (Nicaragua) (individual) [NICARAGUA].

Pursuant to C.F.R 31 § 501.807, OFAC has determined that circumstances no longer warrant the inclusion of the above-named person on the SDN List based on criteria contained in Executive Order 13851, ''Blocking Property of Certain Persons Contributing to the Situation in Nicaragua.''

On December 21, 2022, OFAC determined that the aircraft below is unblocked and the aircraft is removed from the SDN List under the relevant sanctions authority listed below.

Aircraft:

1. N488RC; Aircraft Model G200; Aircraft Manufacturer's Serial Number (MSN) 228; Aircraft Tail Number N488RC (aircraft) [VENEZUELA] (Linked To: SARRIA DIAZ, Rafael Alfredo).

Pursuant to C.F.R 31 § 501.807, OFAC has determined that circumstances no longer warrant the inclusion of the above-named aircraft on the SDN List based on criteria contained in Executive Order 13692, ''Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Venezuela.''

Dated: December 21, 2022.

Andrea M. Gacki,

Director,Office of Foreign Assets Control,U.S. Department of the Treasury.

[FR Doc. 2022–28145 Filed 12–23–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is updating the identifying information on its Specially Designated Nationals and Blocked Persons List (SDN List) for two individuals whose property and interests in property subject to U.S. jurisdiction are blocked pursuant to Executive Order 13224, as amended.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action

On December 21, 2022, OFAC published the following revised information for the entries on the SDN List for the following individuals whose property and interests in property are blocked pursuant to Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten To Commit, or Support Terrorism,'' as amended by Executive Order 13886 of September 9, 2019, ''Modernizing Sanctions to Combat Terrorism.''

Individuals:

1. BAYALTUN, Ismail, Atlikonak Koyu Koyichi Shanliurfa, Merkez, Shanliurfa, Turkey; DOB 21 Nov 1980; POB Akcakale, Turkey; nationality Turkey; citizen Turkey; Gender Male; Identification Number 43951946270 (Turkey) (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

2. BAYALTUN, Ahmet, Atlikonak Mahallesi, Atlikonak Sokak, No:13, Eyyubiye, Shanliurfa, Turkey; DOB 21 Nov 1989; POB Akcakale, Turkey; nationality Turkey; citizen Turkey; Gender Male; Identification Number 43942946562 (Turkey) (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

Dated: December 21, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–28143 Filed 12–23–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Domestic Production Activities Deduction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning domestic production activities deduction.

DATES: Written comments should be received on or before February 27, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include OMB control number 1545–1984 or Domestic Production Activities Deduction.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis at (202) 317–5751, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.L.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Domestic Production Activities Deduction.

OMB Number: 1545–1984.

Form Number: 8903.

Abstract: Taxpayers will use Form 8903 and related instructions to calculate the domestic production activities deduction.

Current Actions: There is no change to the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 30,000.

Estimated Time Per Respondent: 24 hours, 40 minutes.

Estimated Total Annual Burden Hours: 739,800 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 20, 2022.

Kerry L. Dennis,

Tax Analyst.

[FR Doc. 2022–28038 Filed 12–23–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Rental Assistance Program (ERA2)

AGENCY: Office of Recovery Programs, U.S. Department of the Treasury.

ACTION: Notice of information collection; request for comment.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on this continuing information collection, as required by the Paperwork Reduction Act of 1995. The public is invited to submit comments on the collection(s) listed below.

DATES: Written comments must be received on or before January 26, 2023.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to Melody Braswell, Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8142, Washington, DC 20220, or email at *PRA@treasury.gov.* Copies of submissions may be obtained from Jeff Schroeder by emailing *jeffrey.schroeder@treasury.gov* or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION: On March 11, 2021, the President signed the American Rescue Plan Act of 2021 (the ''Act'') into law. The Act authorizes the Secretary of the Treasury to disburse $21.55 billion of Emergency Rental Assistance (ERA2) to States, the District of Columbia, U.S. Territories, and certain local governments with more

than 200,000 residents (collectively, ''grantees'') to provide financial assistance and housing stability services to eligible households. Beginning on October 1, 2022, eligible ERA2 grantees that have obligated 75% of the ERA2 funds allocated to them may also use their remaining unobligated funds on other affordable rental housing and eviction prevention activities, as defined by the Secretary, serving very low-income families.

Title: Emergency Rental Assistance Program (ERA2).

OMB Control Number: 1505–0270.

Type of Review: Revision a previously approved collection.

Quarterly Reporting

Description

All ERA2 grantees must submit quarterly reports to Treasury detailing their uses of funds to ensure their compliance with the ERA2 Award Terms, the Act, and other applicable requirements. To collect this information, Treasury developed ERA2 quarterly report forms, the accompanying bulk upload templates, and associated guidance. Grantees are required to submit the quarterly reports electronically via Treasury's portal. The current OMB control number for the ERA2 quarterly report forms will expire on December 30, 2022.

Treasury is requesting OMB's approval of additions to and an extension of the ERA2 quarterly report data collection forms. The proposed additions include new questions necessary to monitor the grantees' uses of ERA2 funds to support affordable rental housing and eviction prevention activities starting on October 1, 2022, as authorized by the Act. The remainder of the report, which has been previously approved by OMB, is unchanged.

All information collected through the quarterly reporting is crucial to Treasury's effective monitoring of the ERA2 grantees' compliance with the requirements of the ERA2 award.

Form: Interim Reports,[1] ERA2 Quarterly Reports, Bulk Upload Template, and Guidance.

Affected Public: States, Territories, and local governments who received ERA2 awards.

Estimated Number of Respondents: 376.

Frequency of Response: Quarterly.

Estimated Total Number of Annual Responses: 1,504.

Estimated Time per Response: 30 hours.

Estimated Total Annual Burden Hours: 45,120 hours.

Reallocation

Description

The Act requires Treasury to reallocate funds initially allocated, but not yet paid, to eligible grantees, according to a procedure established by Treasury. Pursuant to the reallocation procedure Treasury has established, Treasury identifies funds subject to reallocation on a quarterly basis and refers to them as ''excess funds.'' To identify the eligible grantees interested in receiving reallocated funds, Treasury solicits Request for Reallocation forms through its ERA2 program portal, which capture the amount of each grantee's request as well as information confirming that a requesting grantee meets certain eligibility requirements, including the statutory requirement that a grantee obligate at least 50% of its initial ERA2 allocation before receiving reallocated funds.

In addition to confirming grantees' eligibility to receive reallocated funds, the reallocation forms on Treasury's ERA2 portal allow Treasury to collect information needed to determine which grantees to prioritize in the distribution of reallocated funds. Treasury's prioritization calculation considers: whether potential recipient grantees are located in the same state as transferor grantees; potential recipient grantees' rate of expenditure; and potential recipient grantees' jurisdictional needs. Pursuant to Treasury's ERA2 program guidance, starting with reallocation based on data as of June 30, 2022 (known as the Quarter 2 Assessment), Treasury will also prioritize, among eligible grantees, those grantees that have expended non-ERA funds, including State and Local Fiscal Recovery Funds, for rental or utility assistance substantially similar to eligible uses under ERA1 [2] or ERA2 since the enactment of the ERA1 statute on December 27, 2020, in an amount exceeding 20% of their initial ERA2 allocation. To receive this prioritization, a grantee must submit to Treasury a certification of, among other things, the amount of non-ERA funding expended on rental or utility assistance substantially similar to eligible uses under ERA1 or ERA2, the sources of these expenditures, and the number of households served. To implement this prioritization system for the Quarter 2 Assessment and subsequent reallocation cycles, Treasury has developed a form for its reallocation portal to collect information needed to confirm that a requesting eligible grantee is entitled to prioritization based on its non-ERA expenditures.

In addition to the above-described reallocation process, some grantees choose to voluntarily reallocate a portion of their ERA2 allocations to one or more eligible grantees. To that end, Treasury has also developed, within its reallocation portal, a standard form that grantees use to initiate voluntary reallocation. In accordance with statutory requirements, a grantee may transfer up to 60% of its initial ERA2 allocation.

OMB approved the usage of these various reallocation forms on June 16, 2022. Since then, Treasury has made *de minimis* changes accounting for the passage of time and other program developments, none of which substantively alter the forms.

Accordingly, the collection of the above-described information is crucial to the reallocation process, which is a central component of the ERA2 program.

Forms: Request for Voluntary Reallocation; Request for Reallocated Funds; Request for Reallocated Funds—Voluntary; Non-ERA Expenditures Report.

Affected Public: States, Territories and local governments who received ERA2 awards.

Estimated Number of Respondents: 482.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 982.

Estimated Time per Response: Varies from 10–60 minutes.

Estimated Total Annual Burden Hours: 524.4 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2022–28138 Filed 12–23–22; 8:45 am]

BILLING CODE 4810–25–P

[1] Treasury is not currently collecting interim reports but is seeking approval of the documents in the event that they become necessary again in the future. Accordingly, they are not accounted for in the hourly burden calculations.

[2] ''ERA1'' refers to the Emergency Rental Assistance program authorized by the Consolidated Appropriations Act, 2021, Pub. L. 116–260, section 501, 134 Stat. 2069 (Dec. 27, 2020).

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0876]

Agency Information Collection Activity under OMB Review: Clearance for A–11 Section 280 Improving Customer Experience Information Collection

AGENCY: Veterans Experience Office, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Experience Office, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''Clearance for A–11 Section 280 Improving Customer Experience Information Collection'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0876'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Clearance for A–11 Section 280 Improving Customer Experience Information Collection.

OMB Control Number: 2900–0876.

Type of Review: ICR Revision.

Abstract: This ICR Revision seeks to extend the expiration date that currently expires in March 2023, and increase the burden hours associated with the Department of Veterans Affairs customer experience data collection system from 1,754,975 to 2,504,975, and the number of responses from 3,500,000 to 5,000,000.

VA, when it submitted the original Clearance for A–11 Section 280 Improving Customer Experience Information Collection, calculated total the burden needed based on the number of Customer Satisfaction surveys under management (43 in calendar year 2020) and our informed estimate of growth in number of surveys under management. As a result of unexpectedly strong and robust need (and corresponding requests) for new customer experience surveys by VA customers (stakeholders and partners), VA has already reached 147 surveys under management and anticipate reaching 200 by the end of Fiscal Year 2023. This anticipated FY23 growth, and per our models for growth from now until our current ICR expires in March, 2023, directly translates into a corresponding need for an increase in associated burden hours from 1,754,975 to 2,504,975, and the number of responses from 3,500,000 to 5,000,000, to accommodate the current and future demand.

General Background on our Customer Experience data collection listening tools

Whether seeking a loan, Social Security benefits, Veterans benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector. A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. Veterans Experience Office will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. Veterans Experience Office will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. Veterans Experience Office may also utilize observational techniques to collect this information.

Collections will be targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future. For the purposes of this request, ''customers'' are individuals, businesses, and organizations that interact with a Federal Government agency or program, either directly or via a Federal contractor. This could include individuals or households; businesses or other for-profit organizations; not-for profit institutions; State, local or tribal governments; Federal government; and Universities.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 84 FR 149 on August 2, 2019, pages 37953 and 37954. No comments on this data collection request were submitted by the public.

Affected Public: Individuals or Households.

Estimated Annual Burden: 2,504,975.

Estimated Average Burden per Respondent: Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 2 minutes or up to 2 hours to participate in an interview.

Frequency of Response: Varied, dependent upon the data collection method used.

Estimated Number of Respondents: 5,000,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–28064 Filed 12–23–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0568]

Agency Information Collection Activity: Submission of School Catalog to the State Approving Agency

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. DATES: Written comments and recommendations on the proposed collection of information should be received on or before February 27, 2023.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0568 in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0568'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA. With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Title 38 U.S.C. 3675; 3676; 38 CFR Sections 21.4253 and 21.4254.

Title: Submission of School Catalog to the State Approving Agency.

OMB Control Number: 2900–0568.

Type of Review: Revision of a currently approved collection.

Abstract: State Approving Agencies and VA use the catalogs to determine what courses can be approved for VA training. VA receives catalogs when institutions change their education programs, tuition and fees and calendars, etc. In general, the catalogs are collected twice a year. Without the catalogs, VA and SAAs cannot determine what courses could be approved. There was a decrease in burden during this renewal period because, unlike for the previous submission, we now take the annual average number of catalogs received during periods 2019, 2020 and 2021, rather than the actual grand total of the number of catalogs received for those periods.

Affected Public: Individuals or Households.

Estimated Annual Burden: 891 hours.

Estimated Average Burden Time per Respondent: 15 minutes.

Frequency of Response: Twice Annually.

Estimated Number of Respondents: 3,567.

By direction of the Secretary:

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–28118 Filed 12–23–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 417, et al.

Office of the Secretary

45 CFR Part 170

Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 417, 422, 423, 455, and 460

Office of the Secretary

45 CFR Part 170

[CMS–4201–P]

RIN 0938–AU96

Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

AGENCY: Centers for Medicare & Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, medication therapy management, marketing and communications, health equity, provider directories, coverage criteria, prior authorization, passive enrollment, network adequacy, identification of overpayments, formulary changes, and other programmatic areas. This proposed rule would also codify regulations implementing section 118 of Division CC of the Consolidated Appropriations Act, 2021, section 11404 of the Inflation Reduction Act, and includes a large number of provisions that would codify existing sub-regulatory guidance in the Part C, Part D, and PACE programs. This proposed rule would also amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an identified overpayment.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 13, 2023.

ADDRESSES: In commenting, please refer to file code CMS–4201–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–4201–P, P.O. Box 8013, Baltimore, MD 21244.

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–4201–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:

Catherine Gardiner, (410) 786–7638—General Questions.

Katie Parker, (410) 786–0537—Parts A and B Overpayment Provision.

Carly Medosch, (410) 786–8633—Part C and Cost Plan Issues.

Lucia Patrone, (410) 786–8621– Part D Issues.

Nathan Jessen, (608) 520–1837—Part D Issues.

Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeals Issues.

Kelley Ordonio, (410) 786–3453—Parts C and D Payment Issues; Parts C and D Overpayment Provisions.

Hunter Coohill, (720) 853–2804—Enforcement Issues.

Lauren Brandow, (410) 786–9765—PACE Issues.

Melissa Seeley, (212) 616–2329—D–SNP Issues.

Alexander Baker, (202) 260–2048—Health IT Standards.

PartCandDStarRatings@cms.hhs.gov—Parts C and D Star Ratings 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.

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C), Medicare Cost Plan, and Medicare Prescription Drug Benefit (Part D) programs, and Programs of All-Inclusive Care for the Elderly (PACE). This proposed rule includes a number of new policies that would improve these programs as well as codify existing Part C and Part D sub-regulatory guidance. This proposed rule would also amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an identified overpayment.

Additionally, this rule implements certain sections of the following Federal laws related to the Parts C and D programs:

- The Inflation Reduction Act (IRA) of 2022.
- The Consolidated Appropriations Act (CAA), 2021.
- The Bipartisan Budget Act (BBA) of 2018.
- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018.

B. Summary of the Major Provisions

1. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

In this rule, we are proposing a health equity index (HEI) reward for the 2027 Star Ratings to further incentivize Parts C and D plans to focus on improving care for enrollees with social risk factors (SRFs); as part of this change, we are also proposing to remove the current reward factor. This proposal supports CMS efforts to ensure attainment of the highest level of health for all people. We are proposing to reduce the weight of

patient experience/complaints and access measures to further align efforts with other CMS quality programs and the current CMS Quality Strategy, as well as to better balance the contribution of the different types of measures in the Star Ratings program. We are also proposing to remove the Part C Diabetes Care—Kidney Disease Monitoring and the stand-alone Medication Reconciliation Post-discharge measures; add the Part C Kidney Health Evaluation for Patients with Diabetes and the updated Colorectal Cancer Screening and Care for Older Adults—Functional Status Assessment measures; add the Part D Concurrent Use of Opioids and Benzodiazepines, Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults, and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measures; and update the Part D Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. We are proposing to remove guardrails (that is, bi-directional caps that restrict upward and downward movement of a measure's cut points for the current year's measure-level Star Ratings compared to the prior year's measure-threshold specific cut points) when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures; modify the Improvement Measure hold harmless policy; add a rule for the removal of Star Ratings measures; and remove the 60 percent rule that is part of the adjustment for extreme and uncontrollable circumstances (also called the disaster adjustment). We are also proposing a series of technical clarifications related to the disaster adjustment, Quality Bonus Payment (QBP) appeals processes, treatment of ratings for contracts after consolidation, weighting of measures with a substantive specification change, and addressing the codification error related to use of Tukey outlier deletion. These changes would apply (that is, data would be collected and performance measured) for the 2024 measurement period and the 2026 Star Ratings, except for the removal of the Part C Diabetes Care—Kidney Disease Monitoring measure, which would apply for the 2022 measurement period and the 2024 Star Ratings; the HEI reward, which would include data from the 2024 and 2025 measurement periods and apply for the 2027 Star Ratings; and the risk adjustment based on sociodemographic status characteristics to the three adherence measures, which would be implemented for the 2026 measurement period and the 2028 Star Ratings.

2. Medication Therapy Management (MTM) Program (§ 423.153)

Section 1860D–4(c)(2) of the Act requires all Part D sponsors to have an MTM program 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. Section 1860D–4(c)(2)(A)(ii) of the Act requires Part D sponsors to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. CMS codified the MTM targeting criteria at § 423.153(d)(2).

Part D sponsors currently have significant flexibility in establishing their MTM eligibility criteria within the established framework. CMS has observed decreasing eligibility rates and near-universal convergence among Part D sponsors to the most restrictive criteria currently permitted. Due to the increasing cost threshold and variations in the targeting criteria implemented by sponsors, Part D enrollees with more complex drug regimens who would benefit most from MTM services are often not eligible. In addition, enrollees with equivalent patient profiles may or may not be eligible for MTM depending on the criteria their plan requires.

After an extensive analysis to identify potential disparities in MTM program eligibility and access, CMS is proposing changes to the MTM targeting criteria at § 423.153(d)(2) to promote consistent, equitable, and expanded access to MTM services. The combination of proposed changes includes: (1) requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current 9 core chronic diseases [1] in regulation, and adding HIV/AIDS for a total of 10 core chronic diseases; (2) lowering the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and (3) revising the methodology for calculating the cost threshold ($4,935 in 2023) to be commensurate with the average annual cost of 5 generic drugs ($1,004 in 2020). The proposed changes would reduce eligibility gaps so that more Part D enrollees with complex drug regimens at increased risk of medication therapy problems would be eligible for MTM services. They would also better align MTM eligibility criteria with statutory goals to reduce medication errors and optimize therapeutic outcomes for beneficiaries with multiple chronic conditions and taking multiple Part D drugs, while maintaining a reasonable cost criterion.

In this rule, we are also proposing to codify longstanding CMS guidance that a beneficiary is unable to accept an offer to participate in the comprehensive medication review (CMR) only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. We are also proposing other technical changes to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth.

3. Strengthening Translation and Accessible Format Requirements for Medicare Advantage, Part D, and D–SNP Enrollee Marketing and Communication Materials (§§ 422.2267 and 423.2267)

Sections §§ 422.2267(a)(2) and 423.2267(a)(2) require MA organizations, cost plans, and Part D sponsors to translate required materials into any non-English language that is the primary language of at least 5 percent of individuals in a plan benefit package service area. In addition, 45 CFR 92.102(b) requires plans to provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. However, CMS has learned from oversight activities, enrollee complaints, and stakeholder feedback that enrollees often must make a separate request each time they would like a material in an alternate language or need auxiliary aids or services.

In addition, an increasing number of dually eligible individuals are enrolled in managed care plans where the same plan covers both Medicare and Medicaid services. In some cases, Medicaid standards for Medicaid managed care plans require translation of plan materials into a language not

[1] The current core chronic diseases are: diabetes*, hypertension*, dyslipidemia*, chronic congestive heart failure*, Alzheimer's disease, end stage renal disease (ESRD), respiratory disease (including asthma*, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders), bone disease-arthritis (osteoporosis, osteoarthritis, and rheumatoid arthritis), and mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions). Enumerated in statute (*).

captured by the Medicare Advantage requirements.

We are proposing to specify in Medicare regulations that MA organizations, cost plans, and Part D sponsors must provide materials to enrollees on a *standing basis* in any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area or accessible format using auxiliary aids and services upon receiving a request for the materials or otherwise learning of the enrollee's preferred language and/or need for an accessible format using auxiliary aids and services. We are also proposing at §§ 422.2267(a)(3) and 423.2267(a)(3) to extend this requirement to individualized plans of care for special needs plans. We are also proposing to require that fully integrated dual eligible special needs plans (FIDE SNPs), highly integrated dual eligible special needs plans (HIDE SNPs), and applicable integrated plans (AIPs) as defined at § 422.561, translate required materials into any languages required by the Medicare translation standard at § 422.2267(a) plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

4. Health Equity in Medicare Advantage (MA) (§§ 422.111 and 422.112)

CMS is working to achieve policy goals that advance health equity across its programs and pursue a comprehensive approach to advancing health equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.[2] To that end, we are proposing the following regulatory updates.

First, current regulations require MA organizations to ensure that services are provided in a culturally competent manner. The regulation provides examples of populations that may require consideration specific to their needs. In this proposed rule, we propose to further clarify the broad application of our policy. Specifically, we propose to amend the list of populations to include people: (1) with limited English proficiency or reading skills; (2) of ethnic, cultural, racial, or religious minorities; (3) with disabilities; (4) who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (5) who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (6) who live in rural areas and other areas with high levels of deprivation; and (7) otherwise adversely affected by persistent poverty or inequality.

Next, CMS currently provides best practices for organizations to use in developing their provider directories, including incorporating non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities. In this rule, we propose to codify these best practices by requiring organizations to include providers' cultural and linguistic capabilities (including American Sign Language, ASL) in their provider directories. If finalized, this change would improve the quality and usability of provider directories, particularly for non-English speakers, limited English proficient individuals, and enrollees who use ASL. We are also proposing to require organizations to identify certain providers waived to treat patients with medications for opioid use disorder (MOUD) in their provider directories.

In addition, as the use of telehealth becomes more prevalent, there is evidence of disparities in telehealth access due in part to low digital health literacy, especially among populations who already experience health disparities. Low digital health literacy is one of the most significant obstacles in achieving telehealth equity, and many older adults with low digital health literacy experience gaps in access to the health care they need. This is concerning for the MA program because its enrollee population includes older adults who are age 65 or older, which is why we are proposing to address the issue by requiring MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits.

Finally, MA organizations' existing quality improvement (QI) programs are an optimal vehicle to develop and implement strategies and policies designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved. To support these efforts, we propose to require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees. MA organizations may implement activities such as improving communication, developing and using linguistically and culturally appropriate materials (to distribute to enrollees or use in communicating with enrollees), hiring bilingual staff, community outreach, or similar activities. We believe adopting this proposed requirement for MA organizations as part of their required QI programs will align with health equity efforts across CMS policies and programs.

5. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, 422.138, and 422.202)

In recent years, CMS has received numerous inquiries regarding MA organizations' use of prior authorization and its effect on beneficiary access to care. We are proposing several regulatory changes to address these concerns regarding prior authorization. First, we propose that prior authorization policies for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary based on standards specified in this rule. Second, we propose that an approval granted through prior authorization processes be valid for the duration of the approved course of treatment and that plans provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment switches to a new MA plan. Third, we propose that MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations as interpreted by CMS. Further, we propose that MA plans cannot deny coverage of a Medicare covered item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies. We propose that when there is no applicable coverage criteria in Medicare statute, regulation, NCD, or LCD, MA organizations may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available to CMS, enrollees, and providers.

Finally, to ensure prior authorization is being used appropriately, we propose to require that all MA plans establish a Utilization Management Committee to review all utilization management, including prior authorization, policies

[2] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

annually and ensure they are consistent with current, traditional Medicare's national and local coverage decisions and guidelines. These proposed changes will help ensure enrollees have consistent access to medically necessary care, without unreasonable barriers or interruptions.

6. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

In accordance with our statutory authority to review marketing materials and application forms and to develop marketing standards under sections 1851(h), 1851(j), 1860D–1(b)(1)(vi), and 1860D–4(l) of the Act, as well as the statutory requirements in sections 1852(c) and 1860D–4(a) of the Act requiring MA organizations and Part D sponsors disclose specific types of information to enrollees, we are proposing several changes to 42 CFR parts 422 and 423, subpart V, to strengthen beneficiary protections and improve MA and Part D marketing. These changes include: notifying enrollees annually, in writing, of the ability to opt out of phone calls regarding MA and Part D plan business; requiring agents to explain the effect of an enrollee's enrollment choice on their current coverage whenever the enrollee makes an enrollment decision; requiring agents to share key pre-enrollment information with potential enrollees when processing telephonic enrollments; simplifying plan comparisons by requiring medical benefits be in a specific order and listed at the top of a plan's Summary of Benefits; limiting the time that a sales agent can call a potential enrollee to no more than six months following the date that the enrollee first asked for information; limiting the requirement to record calls between third-party marketing organizations (TPMOs) and beneficiaries to marketing (sales) and enrollment calls; clarifying that the prohibition on door-to-door contact without a prior appointment still applies after collection of a business reply card (BRC) or scope of appointment (SOA); prohibiting marketing of benefits in a service area where those benefits are not available, prohibiting the marketing of information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they sell; requiring MA organizations and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS; modifying the TPMO disclaimer to add SHIPs as an option for beneficiaries to obtain additional help; placing discrete limits around the use of the Medicare name, logo, and Medicare card; prohibit the use of superlatives (for example, words like ''best'' or ''most'') in marketing unless the material provides documentation to support the statement, and the documentation is for the current or prior year; and, clarifying the requirement to record calls between TPMOs and beneficiaries, such that it is clear that the requirement includes virtual connections such as video conferencing and other virtual telepresence methods.

7. Behavioral Health in Medicare Advantage (MA) (§§ 422.112 and 422.116)

As part of the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule, which appeared in the January 12, 2022 **Federal Register** (87 FR 1842) (hereinafter referred to as the January 2022 proposed rule), we solicited comments from stakeholders regarding challenges in building MA behavioral health networks and opportunities for improving access to services. Stakeholders commented on the importance of ensuring adequate access to behavioral health services for enrollees and suggested expanding network adequacy requirements to include additional behavioral health specialty types.

To strengthen our network adequacy requirements and reaffirm MA organizations' responsibilities to provide behavioral health services, we propose to: (1) add Clinical Psychology Licensed Clinical Social Worker, and Prescribers of Medication for Opioid Use Disorder as specialty types that will be evaluated as part of the network adequacy reviews under § 422.116, and make these new specialty types eligible for the 10-percentage point telehealth credit as allowed under § 422.116(d)(5); (2) amend our general access to services standards in § 422.112 to include explicitly behavioral health services; (3) codify, from existing guidance on reasonable wait times for primary care visits, standards for wait times that apply to both primary care and behavioral health services; (4) clarify that some behavioral health services may qualify as emergency services and, therefore, must not be subject to prior authorization; and (5) extend current requirements for MA organizations to establish programs to coordinate covered services with community and social services to behavioral health services programs to close equity gaps in treatment between physical health and behavioral health.

8. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

CMS requires notification to MA enrollees when a provider network participation contract terminates. CMS is proposing to revise § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS is also proposing to revise § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.

9. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program (§§ 423.2500–423.2536)

CMS has operated the LI NET demonstration since 2010. The LI NET demonstration provides transitional, point-of-sale coverage for low-income beneficiaries who demonstrate an immediate need for prescriptions, but who have not yet enrolled in a Part D plan, or whose enrollment is not yet effective. LI NET also provides retroactive and/or temporary prospective coverage for beneficiaries determined to be eligible for the Part D low-income subsidy (LIS) by the Social Security Administration (SSA) or a State. In this proposed rule, we propose regulations to make the LI NET program a permanent part of Medicare Part D, as required by the Consolidated Appropriations Act, 2021 (CAA).

10. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 401.305(a)(2), 422.326(c), and 423.360(c))

The proposed regulatory provisions would amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an ''identified overpayment'' and will align the regulations with the statutory language in section 1128J(d)(4)(A) of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False

Claims Act at 31 U.S.C. 3729(b)(1)(A). Specifically, in this regulation we propose to remove the existing ''reasonable diligence'' standard and adopt by reference the False Claims Act definition of ''knowing'' and ''knowingly'' as set forth at 31 U.S.C. 3729(b)(1)(A). Under the proposed rule, an MA organization, Part D sponsor, provider or supplier has identified an overpayment if it has actual knowledge of the existence of the overpayment, or acts in reckless disregard or deliberate ignorance of the overpayment.

11. Changes to an Approved Part D Formulary—Immediate Substitutions (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

Current regulations permit Part D sponsors to immediately remove from the formulary a brand name drug and substitute its newly released generic equivalent. Part D sponsors meeting the requirements can provide notice of specific changes, including direct notice to affected beneficiaries, after they take place; do not need to provide a transition supply of the substituted drug; and can make these changes at any time including in advance of the plan year. Consistent with these requirements, we propose to permit Part D sponsors to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.

12. Expanding Eligibility for Low-Income Subsidies (LIS) Under Part D of the Medicare Program (§§ 423.773 and 423.780)

Section 11404 of the IRA amended section 1860D–14 of the Act to expand eligibility for the full LIS to individuals with incomes up to 150 percent of the Federal poverty level (FPL) beginning on or after January 1, 2024. In addition, the IRA allows for individuals to qualify for the full subsidy based on the higher resource requirements currently applicable to the partial LIS group. This change will provide the full LIS subsidy for those who currently qualify for the partial subsidy, and we are proposing to implement this change in this regulation.

C. Summary of Costs and Benefits

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TABLE 1

Provision	Description	Impact
a. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)	We propose several measure changes and methodological clarifications and enhancements to the Part C and Part D Star Ratings as described in section V. In addition to proposing to establish an HEI reward as a replacement for the current reward factor and to reduce the weight of patient experience/complaints and access measures, we are proposing to: modify the improvement measure highest rating hold harmless provision so it applies only to contracts with 5 stars for their highest rating, remove the cut point guardrails, add a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, remove the 60 percent rule for extreme and uncontrollable circumstances, clarify existing rules around administrative review process for QBP determinations, and clarify additional aspects of the existing Star Ratings calculations.	The HEI reward provision, which would replace the current reward factor, is expected to result in net savings of between $680 million in 2028 and $1.05 billion in 2033, resulting in a ten-year savings estimate of $5.13 billion. The patient experience/complaints and access measure weight provisions are expected to result in net savings of between $330 million in 2027 and $580 million in 2033, which results in a ten year savings estimate of $3.28 billion. For the improvement measure hold harmless provision, net savings are estimated to be between $2.08 billion in 2027 and $3.52 billion in 2033, resulting in a ten-year savings estimate of $19.3 billion. The net impact of all of the Star Ratings proposed provisions is $24.97 billion in savings over ten years accounting for 0.37% of the private health baseline.

Provision	Description	Impact
b. Medication Therapy Management (MTM) Program (§ 423.153)	We propose changes to the MTM targeting criteria to: (1) Require Part D sponsors to include all core chronic diseases in their targeting criteria, codify the current 9 core chronic diseases in regulation, and add HIV/AIDS for a total of 10 core chronic diseases. (2) Lower the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs and require sponsors to include all Part D maintenance drugs. (3) Revise the cost threshold methodology based on the average annual cost of 5 generic Part D drugs ($1,004 in 2020).	We estimate that these proposed changes would increase the number and percentage of Part D enrollees eligible for MTM services from 4.5 million (9 percent) to 11 million (23 percent). The increase in MTM program enrollment is estimated to cost approximately $336 million annually for required MTM services. We cannot definitively score this proposal because there may be other administrative costs attributable to MTM, which is not a specific line item that can be easily extracted from plan bids. Also, there is evidence that MTM services may generate overall medical savings, but we cannot quantify those savings at this time.

Provision	Description	Impact
c. Strengthening Translation Requirements for Medicare Advantage, Cost plans, Part D, and D-SNP Enrollee Marketing and Communication Materials (§§ 422.2267 and 423.2267)	We propose to require that: (1) MA organizations, cost plans, and Part D sponsors provide materials to enrollees on a *standing basis* in any non-English languages that is the primary language of at least 5 percent of the individuals in that service area and/or accessible formats using auxiliary aids and services; and (2) fully integrated D-SNPs (FIDE SNPs), highly integrated D-SNPs (HIDE SNPs) and applicable integrated plans (AIPs) translate both Medicare and Medicaid materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.	(1) We estimate the proposal to require MA organizations, cost plans, and Part D sponsors to establish a process to provide materials to enrollees on a standing basis would cost $10.4 million. We expect that implementing a standing request process would reduce future costs to MA organizations, cost plans, and Part D sponsors by decreasing rework of sending two sets of information, one in the incorrect language or format and the other in the correct format. (2) We estimate it would cost $2.1 million for FIDE SNPs, HIDE SNPs, and AIPs to translate one set of materials into one additional language. Any additional documents needing translation would be a one-time cost with a smaller cost to update the documents in future contract years.

Provision	Description	Impact
d. Health Equity in Medicare Advantage (MA) (§§ 422.111 and 422.112)	We propose to: (1) clarify the broad application of our policy that MA services be provided in a culturally competent manner, (2) require each provider's cultural and linguistic capabilities and notations for certain MOUD-waivered providers be included in all MA provider directories, (3) require MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered telehealth benefits, and (4) require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees.	(1) Expanding the list of populations is proposed for purposes of clarity, and is not expected to have any economic impact on the Medicare Trust Fund. (2) Codifying providers' cultural and linguistic capabilities and notations for certain MOUD-waivered providers as required provider directory data elements is not expected to have any economic impact on the Medicare Trust Fund. (3) Our proposal requiring MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy is expected to have an unknown economic impact on the Medicare Trust Fund. (4) Aligning MA QI programs with health equity efforts across CMS policies and programs is not expected to have any economic impact on the Medicare Trust Fund.

Provision	Description	Impact
e. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Mandate Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137 and 422.138422.4)	We propose to: 1) require MA plans to follow Traditional Medicare coverage NCDs, LCDs, statutes and regulations when making medical necessity determinations, 2) require plans to provide a public summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, 3) require that an approval granted through PA processes must be valid for the duration of a prescribed course of treatment and that plans are required to provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment switches to a new MA plan, switches from Traditional Medicare to an MA plan, or is new to Medicare, and 4) require MA organizations to establish a committee, led by the Medical Director, that reviews utilization management, including PA, policies annually and keeps current of LCDs, NCDs, and other Traditional Medicare coverage policies.	(1) Require MA plans to follow Traditional Medicare coverage guidelines when making medical necessity determinations. The impact is difficult to quantify. (2) Requires plans to post a public summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations. (3) Requires PA approval to be valid for the duration of the approved course of treatment and is not expected to have economic impact on the Medicare Trust fund. (4) Require MA organizations to establish a committee (similar to a P&T committee), led by the Medical Director, that reviews utilization management, including PA, policies annually and keeps current of LCDs, NCDs, and other Traditional Medicare coverage policies. This is qualitatively beneficial for enrollees and is not expected to have economic impact on the Medicare Trust fund.

Provision	Description	Impact
f. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)	We propose several changes to strengthen beneficiary protections and improve MA and Part D marketing. Examples include notifying enrollees annually, in writing, of the ability to opt out of plan business; requiring agents to explain the effect of an enrollee's enrollment choice on their current coverage; clarifying that the prohibition on door-to-door contact still applies solely based on collection of a business reply card (BRC) or scope of appointment (SOA); prohibiting marketing of benefits in a service area where those benefits are not available, prohibiting the marketing of savings available based on a comparison of typical expenses borne by uninsured individuals; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they sell; requiring plans and sponsors to have an oversight plan that monitors agent/broker activities and reports non-compliance to CMS; adding SHIPs to the TPMO disclaimer as an option for beneficiaries to obtain additional help; placing discrete limits around the use of the Medicare name, logo, and Medicare card; prohibit the use of superlatives unless the material provides documentation to support the statement; and, clarifying the requirement to record calls between TPMOs and beneficiaries includes virtual connections such as Zoom and Facetime.	We recognize the impact of these provisions to be primarily one of changes to Plans' policy and procedure documents. We have tallied the one-time costs of these changes to be $172,593 ($76.20/hr * 2265 hr). We believe there would be an impact of time and cost to Plans for the requirement to report non-compliant agents and brokers to CMS. We are unable to estimate that cost at this time, however, and have solicited comment on how we could accurately do so.

Provision	Description	Impact
g. Behavioral Health in Medicare Advantage (MA) (§§ 422.112 and 422.116)	We propose to add Clinical Psychology Licensed Clinical Social Worker, and Prescribers of Medication for Opioid Use Disorder, as specialty types that will be evaluated using the time, distance and minimum provider standards in our network adequacy reviews; amend our access to services standards to include behavioral health services; codify minimum access wait time standards (from current example wait times for primary care) to apply to both primary care and for behavioral health services; clarify that behavioral health services may qualify as emergency services and therefore not be subject to prior authorization when furnished as emergency services; and require plans to establish behavioral health care coordination programs to ensure enrollees are offered the behavioral health services to which they are entitled to close gaps in behavioral health treatment.	We estimate negligible costs for this proposal.
h. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)	CMS requires notification to enrollees when a provider network participation contract terminates. CMS is proposing to revise § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS is also proposing to revise § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.	This proposal is not expected to have any economic impact on the Medicare Trust Fund.

Provision	Description	Impact
i. Limited Income Newly Eligible Transition (LI NET) Program	We propose to make the longstanding demonstration program a permanent part of Medicare Part D, as directed by the CAA.	The projected costs, estimated by OACT, are the same as what the government would have incurred if the demonstration continued. Further, the costs of the payments provided for under this program will continue, as under the demonstration, to be covered through the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance (SMI) Trust Fund. The provision is estimated to cost the Medicare Trust Fund $95 million over 10 years. There is an additional 10 year paperwork burden of $2.6 million.
j. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c), (§ 401.305(a)(2))	We propose to remove the "reasonable diligence" standard and adopt by reference the "knowledge" standard set forth in the False Claims Act at 31 U.S.C. 3729(b)(1).	We do not have a basis for estimating the impact on new Parts A, B, C and D overpayment recoveries.
k. Changes to an Approved Part D Formulary - Immediate Substitutions	We propose to permit Part D sponsors to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.	We estimate no significant impact to the Medicare Trust Fund or other paperwork burden as a result of this specific proposal.
l. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)	We propose to implement section 11404 of the IRA to expand eligibility for the full LIS subsidy group to individuals currently eligible for the partial LIS subsidy beginning on or after January 1, 2024	We estimate that this change will increase Medicare spending by $2.3 billion over 10 years.

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II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018, the Consolidated Appropriations Act, 2021, and the Inflation Reduction Act of 2022

A. Applying D–SNP Look-Alike Requirements to Plan Benefit Package Segments (§§ 422.503(e), 422.504, 422.510 and 422.514)

In the final rule titled ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program'' which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796) (hereinafter referred to as the June 2020 final rule), CMS finalized the contracting limitations for D–SNP look-alikes at § 422.514(d) and the associated authority and procedures for transitioning enrollees from a D–SNP look-alike at § 422.514(e). For plan year 2022 and subsequent years, as provided in § 422.514(d)(1), CMS will not enter into a contract for a new non-SNP MA plan 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. For plan year 2023 and subsequent years, as provided in § 422.514(d)(2), CMS will not renew a contract with a non-SNP MA plan that 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.

We established these contract limitations to address the proliferation and growth of D–SNP look-alikes, which raised concerns related to effective implementation of requirements for D–SNPs established by section 1859 of the Act (including amendments made by the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) and the Bipartisan Budget Act of 2018 (Pub. L. 115–123)). We adopted the regulation to ensure full implementation of requirements for D–SNPs, such as contracts with State Medicaid agencies; a minimum integration of Medicare and Medicaid benefits; care coordination through health risk assessments (HRAs); evidence-based models of care. In addition, we noted how limiting these D–SNP look-alikes would address beneficiary confusion stemming from misleading marketing practices by brokers and agents that misrepresent to dually eligible individuals the characteristics of D–SNP look-alikes. For a more detailed discussion of D–SNP look-alikes and their impact on the implementation of D–SNP Medicare and Medicaid integration, we direct readers to the June 2020 final rule (85 FR 33805 through 33820) and the 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 (85 FR 9018 through 9021) (also known as the February 2020 proposed rule). We are proposing amendments to close unforeseen loopholes in the scope of the regulation adopted to prohibit D–SNP look-alikes.

1. Applying Contracting Limitations for D–SNP Look-Alikes to MA Plan Segments

As written at § 422.514(d) and (e), the contracting limitations for D–SNP look-alikes are based on analysis at the MA plan level. Section 1854(h) of the Act authorizes MA organizations to segment an MA plan and apply the uniformity requirements for MA plans at the segment level, provided that the segments are comprised of one or more MA payment areas. As implemented in §§ 422.2 (defining ''MA plan''), 422.100(d), 422.254, and 422.262, MA plans may include multiple segments in an MA plan in which different benefit designs, cost-sharing, and premiums are available; bids are submitted at the segment level if an MA plan is segmented and evaluation of compliance with MA requirements is done at the segment level where appropriate. See § 422.100(f)(6) providing for evaluation of cost-sharing at the segment level for segmented plans. In effect, each segment of an MA plan is like a plan itself. We discussed in the Medicare Program; Medicare+Choice Program (65 FR 40170, 40204 through 40205) final rule, which appeared in the **Federal Register** on June 29, 2000 (also known as the June 2000 final rule) how the authority in section 1854(h) of the Act for an MA organization to segment an MA plan has practical implications that are similar to offering multiple plans. One or more segments can be part of the same MA plan even though the Medicare Part C benefits, cost-sharing, premiums, and marketing materials can differ. For example, MA plan benefit package H1234–567 could offer multiple segments distinguished by three additional digits, such as H1234–567–001, H1234–567–002, and H1234–567–003. Since adopting § 422.514(d), we have seen MA plans where a specific segment looks like a D–SNP look-alike and would be subject to the contracting prohibitions in § 422.514(d) if the segment were treated as an MA plan. As finalized, § 422.514(d) does not clearly apply to a segment within an MA plan. However, we believe that by applying the D–SNP look-alike contracting limitations only at the MA plan level without applying it to segments of plans, our existing regulation has an unintended and unforeseen loophole through which D–SNP look-alikes could persist, contrary to the stated objectives in our prior rulemaking.

Based on January 2022 Monthly Membership Report (MMR) data, we identified 47 non-SNP MA plans that meet the criteria outlined at § 422.514(d)(2) when we performed our analysis at the plan level. If we were to apply the § 422.514(d)(2) criteria at the MA plan segment level, segments of three additional non-SNP MA plans would be identified as D–SNP look-alikes. The segments in those three plans collectively have approximately 3,000 enrollees. While the number of non-SNP MA plans at the segment level is currently small, this number could grow in the future and provide an opportunity for MA organizations to circumvent the D–SNP look-alike contracting limitations at § 422.514(d). For example, in our analysis of proposed D–SNP look-alike transitions for contract year 2023, two D–SNP look-alikes in contract year 2022 are proposing to transition a combined total of approximately 7,800 D–SNP look-alike enrollees into two new non-SNP MA plan segments, which could create two new D–SNP look-alike segments for contract year 2023.

We propose adding a new paragraph at 42 CFR 422.514(g) to provide that § 422.514(d) through (f) apply to segments of the MA plan in the same way that those provisions apply to MA plans. As a result, CMS will not contract with or renew a contract with a plan segment where the MA plan or segment is not a D–SNP and the enrollment thresholds in paragraph (d)(1) or (d)(2) are met. This proposal, to treat a segment of an MA plan as an MA plan, would be consistent with CMS' annual review of MA plan bids and Medicare cost-sharing, in which each MA plan segment submits a separate bid pricing tool and plan benefit package like an unsegmented MA plan and CMS separately evaluates these submissions for compliance with MA requirements.

As discussed in the June 2020 final rule, CMS implements the contracting prohibition in § 422.514 at the plan level. Where an MA plan is one of several offered under a single MA contract and the MA organization does not voluntarily non-renew the D–SNP look-alike, CMS will sever the D–SNP look-alike from the overall contract using its authority under § 422.503(e) to sever a specific MA plan from a contract and terminate the deemed contract for the look-alike plan (85 FR 33812). However, CMS does not currently have clear regulatory authority to sever a segment from an MA plan to terminate a contract that has only a segment of an MA plan. CMS adopted the severability regulation at § 422.503(e) in the Medicare Program; Establishment of the Medicare+Choice Program interim final rule (63 FR 35103, hereafter known as the June 1998 interim final rule) as part of implementing the statutory authority for MA contracts to cover more than one MA plan. Without amending § 422.503(e), CMS would need to sever the entire MA plan that has the D–SNP look-alike segment such that other segments in that MA plan would be subject to the contracting prohibition and not renewed under § 422.514(d) as proposed to be amended here if the MA organization failed to comply with § 422.514(d). Instead, we propose to amend § 422.503(e) to allow for CMS to sever a segment from an MA plan and allow the remaining segments of that MA plan to continue along with any other MA plans offered under the same contract. We propose to rely on our authority to adopt MA standards under section 1856(b)(1) of the Act and our authority to adopt additional contract terms when necessary and appropriate, and not inconsistent with the MA statute, under section 1857(e)(1) of the Act. Our primary impetus for this proposal relates to D–SNP look-alikes, but our proposal at § 422.503(e) is not specific to D–SNP look-alikes; because each segment of an MA plan is like a plan itself, we believe severability should apply similarly at the plan and segment level. We also propose to amend § 422.504(a)(19) to adopt a new contract term that MA organizations agree not to segment an MA plan in a way that results in a D–SNP look-alike. In conjunction with the proposed amendments to § 422.514(g) to apply the prohibitions on contracting with D–SNP look-alikes to segments of an MA plan, the amendments to § 422.503(e) would allow CMS to eliminate existing D–SNP look-alike segments and the amendments to § 422.504(a)(19) would allow CMS to prevent new D–SNP look-alikes.

2. Applying Contracting Limitations for D–SNP Look-Alikes to Existing MA Plans

We identified a second loophole during our analysis of contract year 2023 MA plan bids to identify any new MA plans that meet the contract limitation at § 422.514(d)(1). An existing (that is, renewing) MA plan that did not meet the criteria in § 422.514(d)(2) (using January 2022 MMR data as provided in paragraph (e)(3)) projected in its contract year 2023 bid that the MA plan would have 80 percent or higher enrollment of dually eligible individuals in 2023. Because this MA plan is not a new MA plan for contract year 2023, the contract prohibition in § 422.514(d)(1) did not apply. To prohibit similar situations in the future, we propose to amend § 422.514(d)(1) to apply it to both new and existing (that is, renewing) MA plans that are not D–SNPs and submit bids with projected enrollment of 80 percent or more enrollees of the plan's total enrollment that are dually eligible for Medicare and Medicaid. We propose to revise paragraph (d)(1) to provide that CMS does not enter into or renew an MA contract for plan year 2024 and subsequent years when the criteria in paragraphs (d)(1)(i) and (ii) are met. We are proposing to begin this prohibition with 2024 because we expect that 2024 will be the first plan year after the final rule adopting this proposal. Pending finalization of this proposal, § 422.514(d)(1) will continue to prohibit contracts with new MA plans that meet the criteria. As contracts for 2022 and 2023 have been awarded as of the time this proposed rule is issued, the earliest our proposed revision to expand the scope of § 422.514(d)(1) can apply is 2024.

3. Contract Limitations for D–SNP Look-Alikes as a Basis for MA Contract Termination (§ 422.510(a)(4))

Finally, we propose an amendment to § 422.510(a)(4), which outlines the bases for termination of an MA contract. Specifically, we propose to add language at § 422.510(a)(4) to add a new paragraph (a)(4)(xvi) that permits CMS to terminate an MA contract when the MA organization meets the criteria in § 422.514(d)(1) or (d)(2). This proposed amendment is consistent with how § 422.514(d) provides that CMS will not enter into or renew an MA contract in certain circumstances. In our view, § 422.514(d) is sufficient authority for the non-renewal, that is termination, of MA contracts when § 422.514(d) applies. However, we believe that adopting a specific provision in § 422.510(a)(4) will avoid any inadvertent ambiguity on this topic and make it clear that the procedures outlined in § 422.510, including notices, timeframes, and appeal rights, apply when CMS does not renew an MA contract based on application of § 422.514(d).

B. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes (§ 423.38)

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L 108–173) established a Part D—Voluntary Prescription Drug Benefit program for Medicare-eligible individuals. The MMA added section 1860D–1(b)(3)(C) of the Act, which authorized the Secretary to establish Part D special enrollment periods (SEP) for Medicare-eligible individuals to enroll in a Part D plan based on exceptional circumstances—that is, an individual may elect a plan or change his or her current plan election when the individual meets an exceptional condition as determined by the Secretary.

The SEPs for exceptional conditions were historically included in our manual instructions rather than through regulation. In 2020, we codified a number of SEPs that we had adopted and implemented through subregulatory guidance as exceptional circumstance SEPs, including the SEP for Individuals Who Enroll in Part B During the Part B General Enrollment Period (GEP) (85 FR 33909). This SEP, as codified at § 423.38(c)(16), allowed individuals who are not entitled to premium-free Part A and who enroll in Part B during the GEP for Part B (January–March) to enroll in a Part D plan. This SEP begins April 1st and ends June 30th, with a Part D plan enrollment effective date of July 1st. This SEP effective date aligns with the entitlement date for Part B for individuals who enroll in Part B during the GEP.

Currently, when an individual enrolls in Part B during the GEP, their Part B enrollment entitlement date is July 1st, regardless of when during the GEP they enrolled. Division CC, title I, subtitle B, section 120 of the Consolidated Appropriations Act, 2021 (CAA) Pub. L 116–260 modified section 1838(a)(2) of the Act, to address the beginning of the entitlement for individuals enrolling during their GEP pursuant to section 1837(e) of the Act. As added by the CAA, section 1838(a)(2)(D)(ii) of the Act requires that, for an individual who enrolls in Part B during the GEP on or

after January 1, 2023, entitlement begins the first day of the month following the month in which the individual enrolled. For example, if an individual enrolls in Part B in February 2023 (during the GEP), their Part B coverage will begin on March 1st.

Based on Medicare enrollment statutory changes made by the CAA described previously, we are proposing to revise the start and end date for the SEP for Individuals Who Enroll in Part B During the Part B GEP to align with the Part B entitlement dates for someone who enrolls in Part B using the GEP that starts January 1, 2023. Accordingly, we are also proposing to revise the effective date of the individual's Part D plan enrollment, which is always July 1st under the current parameters of this Part D SEP. That is, we are proposing to modify § 423.38(c)(16) to provide that on or after January 1, 2023, an individual who is not entitled to premium-free Part A and who enrolls in Part B during the GEP is eligible to use the SEP for Individuals Who Enroll in Part B During the Part B GEP to request enrollment in a Part D plan, and that this SEP will begin when the individual submits the application for Part B, and will continue for the first 2 months of enrollment in Part B. Further, we propose to modify § 438.38(c)(16) to provide that where an individual uses this Part D SEP to request enrollment in a Part D plan, the Part D plan enrollment would be effective the first of the month following the month the Part D plan sponsor receives the enrollment request. For example, an individual who enrolls in Part B on February 10th for a Part B entitlement date of March 1st can use the Part D SEP to request enrollment in a Part D plan during the period from February 10th to April 30th. If the individual submitted an enrollment request for a Part D plan on February 10th and the enrollment is accepted, the effective date of their Part D coverage would be March 1st. Note that an individual's Part D enrollment effective date cannot be prior to the Part A and/or Part B entitlement date, and the individual must also meet other Part D plan eligibility criteria as described in § 423.30(a). Per current practice, the Part D plan would need to confirm that the individual had enrolled in Part B (or Part B and premium Part A) prior to the individual's Part D enrollment effective date. The Social Security Administration (SSA) will have to first process the individual's Part B application and submit that information into SSA systems, which, in turn, would be populated in the CMS enrollment systems, for a Part D plan to have access to that entitlement information.

We expect this proposed change in enrollment and effective dates using this Part D SEP would simplify the enrollment process and reduce the potential for gaps in prescription drug coverage. Also, we believe it will be easier for beneficiaries to understand the effective date of their Medicare coverage using this Part D SEP, as we are proposing that the Part D effective date will be the first of the month following the month the beneficiary submits an enrollment request, which aligns with most Part D enrollment and SEP timeframes. Although the current SEP for Individuals Who Enroll in Part B During the Part B GEP lasts for 3 calendar months, and the proposed timeframe for use of this SEP would be shorter, the proposed timeframe aligns with most of our other Part D SEPs. In addition, this proposed timeframe would provide the individual the opportunity for a Part D plan enrollment effective date that is within 63 days of the Part B entitlement. For individuals who have maintained creditable drug coverage prior to enrolling in Part B, this proposed SEP timeframe will help to ensure that an individual would not incur a Part D late enrollment penalty (LEP). For example, if an individual enrolls in Part B in February and is entitled to Part B effective March 1st, they could enroll in a Part D plan for an effective date of March 1st, April 1st or May 1st, depending on whether the Part D plan sponsor received the enrollment request in February, March or April, respectively. Any of these Part D plan effective dates would provide Part D coverage to an individual who maintained creditable coverage prior to enrolling in Part B in February within the 63-day timeframe to avoid the penalty. Proposing this exceptional condition SEP also supports President Biden's April 5, 2022 Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage, which, among other things, requires agencies to examine policies or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options, and select appropriate coverage, and also examine policies or practices that strengthen benefits and improve access to healthcare providers.

This proposal would revise the timeframes for use of the Part D SEP described in § 423.38(c)(16) based on the change in effective date for GEP enrollments made by section 120 of the CAA. These proposed revisions are needed to align the timeframe for use of this Part D SEP based on new Part B GEP enrollment effective date parameters.

Because an individual may elect a Part D plan only during an election period, Medicare Part D sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible. Our proposal would not add to existing enrollment processes, so we believe any burden associated with this aspect of enrollment processing would remain unchanged from the current practice, and would not impose any new requirements or burden.

All information impacts of this provision have already been accounted for under OMB control number 0938–1378 (CMS–10718). We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

C. Alignment of Part C and Part D Special Enrollment Periods With Medicare Exceptional Condition Enrollment (§§ 422.62 and 423.38)

Section 1851(e)(4)(D) of the Act authorizes the Secretary to create special enrollment periods (SEPs) for an individual to disenroll from an MA plan or elect another MA plan if the individual meets an exceptional condition provided by the Secretary. This authority was originally codified at § 422.62(b)(4) in the June 1998 interim final rule as a general SEP for CMS to apply on an ad hoc basis. (63 FR 35073)

As noted previously, section 1860D–1(b)(3)(C) of the Act authorizes the Secretary to establish Part D SEPs for Medicare-eligible individuals to enroll in a Part D plan if they meet certain exceptional circumstances. This authority was originally codified at § 423.38(c)(8)(ii) (70 FR 4529). The MMA also added section 1860D–1(b)(1)(B) of the Act which provides that in adopting the Part D enrollment process, the Secretary ''shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan under the following provisions of section 1851.''

Historically, we had included in our regulations those MA and Part D SEPs that have been specifically named in the statute, and established SEPs for exceptional conditions in our subregulatory guidance. In the June 2020 final rule, we codified, at §§ 422.62(b) and 423.38(c), respectively, the MA and Part D SEPs that we had adopted and implemented through

subregulatory guidance as exceptional condition SEPs (85 FR 33796). Codifying these SEPs provided transparency and stability to the MA and Part D programs by ensuring that these SEPs are known to plans and beneficiaries.

As required by section 1851(a)(3) of the Act (for the MA program) and section 1860D–1(a)(3)(A) of the Act (for the Part D program) and described in §§ 422.50(a)(1) and 423.30(a)(1)(i), eligibility for MA or Part D plan enrollment requires that an individual first have Medicare Parts A and B for MA eligibility and either Part A or B for Part D eligibility. Individuals who are entitled to premium-free Part A are generally auto-enrolled when they are first eligible, if they are already receiving retirement or disability benefits from the SSA or Railroad Retirement Board, or they may submit an application to enroll in premium-free Part A at any time after meeting the requirements for entitlement. Under normal conditions, individuals who want to enroll in premium Part A, Part B, or both, must submit a timely enrollment request during their Initial Enrollment Period (IEP), the GEP, or an existing SEP for which they are eligible. Those who fail to enroll during their IEP may face a lengthy penalty for late enrollment (life-long for Part B) and a potential gap in coverage. Prior to the enactment of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L 116–260), CMS did not have broad authority to create SEPs based on exceptional conditions for enrollment into Medicare Parts A and B. However, Division CC, title I, subtitle B, Section 120 of the CAA established section 1837(m) of the Act to authorize the Secretary to establish Part B SEPs for individuals who are eligible to enroll in Medicare and meet such exceptional conditions as the Secretary provides. Per section 1818(c) of the Act, the provisions of section 1837 of the Act, excluding subsection (f) thereof, applies to the premium Part A program. This authority to adopt exceptional conditions SEPs for premium Part A and Part B is effective January 1, 2023. The ability to grant SEPs for exceptional conditions is an important tool that will allow CMS to provide relief to individuals who missed an opportunity to enroll in Medicare due to circumstances that were outside of their control, ensure continuous health coverage, and avoid late enrollment penalties on the premium Part A or Part B premiums. CMS finalized new exceptional condition SEPs under section 1837(m) of the Act in 42 CFR 406.27 and 407.23 for Medicare parts A and B, respectively, in a final rule that was published in the **Federal Register** on November 3, 2022, titled ''Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules'' (87 FR 66454). These SEPs would be available to individuals who have missed an enrollment period due to an exceptional condition that is specified in the final rule. Specifically, individuals who miss an IEP, GEP, or another SEP, such as the Group Health Plan SEP, due to a specified exceptional condition, would be eligible to enroll in Medicare premium Part A or Part B using the new SEPs.

Based on Medicare enrollment changes made by the CAA described previously, we are proposing to add corresponding exceptional condition SEPs for MA and Part D enrollment, as authorized under sections 1851(e)(4)(D) and 1860D–1(b)(3)(C) of the Act, to align with the new Medicare premium Part A and B exceptional condition SEPs that CMS has finalized in 42 CFR 406.27 and 407.23. These new Medicare Part C and D SEPs would be based on an individual's use of a Medicare premium Part A or Part B exceptional conditions SEP. That is, individuals who use an exceptional condition SEP to enroll in premium Part A and/or Part B will be provided an opportunity to enroll in a MA or Part D plan, provided that the individual meets applicable eligibility requirements for the plan.

We are proposing at § 422.62(b) to redesignate current paragraphs (26) as (27) and add a new paragraph (26) to provide an SEP for individuals to enroll in a MA plan or MA plan that includes Part D benefits (MA–PD plan), when they use a Medicare exceptional condition SEP to enroll in premium Part A and/or Part B. We are also proposing at § 423.38(c) to redesignate current paragraph (34) as (35) and add new paragraph (34) to provide an SEP for individuals to enroll in a stand-alone Part D prescription drug plan (PDP) when they use a Medicare exceptional condition SEP to enroll in premium Part A or Part B.

The proposed new MA SEP would begin when the individual submits the application for premium Part A and Part B, or only Part B, and would continue for the first 2 months of enrollment in Part A (premium or premium-free) and Part B. Similarly, the proposed new Part D SEP would begin when the individual submits their premium Part A or Part B application and would continue for the first 2 months of enrollment in premium Part A or Part B. The MA or Part D plan enrollment would be effective the first of the month following the month the MA or Part D plan receives the enrollment request. For example, an individual who enrolls in premium Part A or Part B using an exceptional conditions SEP, as codified in 42 CFR 406.27 and 407.23, on July 10th for an entitlement ate of August 1st, can use the MA or Part D exceptional circumstance SEP to request enrollment in a MA or Part D plan during the period from July 10th to September 30th. If the individual submitted an enrollment request for an MA or Part D plan on July 10th and the enrollment is accepted, the effective date of their MA or Part D coverage would be August 1st.

An individual's MA or Part D plan enrollment effective date cannot be prior to the Part A and/or Part B enrollment date, and the individual must also meet other MA or Part D plan eligibility criteria as described in §§ 422.50(a) or 423.30(a), respectively, in order to use the new MA or Part D SEP we are proposing. Per current practice, the MA or Part D plan would need to confirm that the individual had enrolled in premium Part A and/or Part B, as applicable, using one of the new SEPs for exceptional conditions prior to the individual's MA or Part D enrollment effective date. The SSA will have to first process the individual's premium Part A and/or Part B application and submit that information into SSA systems, which, in turn, would be populated in the CMS enrollment systems, for an MA or Part D plan to have access to that enrollment information.

Providing an opportunity for Part D enrollment at the time of Medicare premium Part A or Part B enrollment using an exceptional condition SEP will help ensure that an individual will have timely access to Part D drugs, within the timeframe of 63 days [3] established in regulation at § 423.46(a), to prevent a Part D late enrollment penalty from being assessed. For example, if an individual enrolls in premium Part A or Part B using an exceptional condition SEP in July and is entitled to premium Part A and/or Part B effective August 1st, they could enroll in a Part D plan

[3] 42 CFR 423.46(a) states that, a Part D eligible individual must pay the late penalty described under § 423.286(d)(3), except as described at § 423.780(e), if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan.

(2) The individual was not covered under any creditable prescription drug coverage.

(3) The individual was not enrolled in a Part D plan.

for an effective date of August 1st, September 1st, or October 1st, depending on whether the Part D plan sponsor received the enrollment request in July, August, or September respectively. Any of these Part D plan effective dates would provide an individual with Part D coverage within the 63-day timeframe of Medicare eligibility to avoid the penalty. This is an important beneficiary protection, especially for those individuals who have to bear the cost of paying a premium for Part A.

This proposed MA exceptional condition SEP will allow beneficiaries who are enrolled in premium Part A and in Part B to exercise their option to receive their healthcare from an MA plan, instead of Original Medicare, as soon as the individual is enrolled in both Parts A and B, without waiting for the annual coordinated election period. Proposing exceptional condition SEPs for MA and Part D also supports President Biden's April 5, 2022 E.O. on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage, which, among other things, requires agencies to examine policies or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options, and select appropriate coverage, and also examine policies or practices that strengthen benefits and improve access to healthcare providers.

Because an individual may elect an MA or Part D plan only during an election period, MA organizations and Part D sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible. Our proposal would not add to existing enrollment processes, so we believe any burden associated with this aspect of enrollment processing would remain unchanged from the current practice, and would not impose any new requirements or burden.

Consequently, this provision will not have added impact. All burden impacts of these provisions have already been accounted for under OMB control number 0938–1378 (CMS–10718). We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

D. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program (§§ 423.2500 through 423.2536)

1. Background on the LI NET Demonstration and Introduction to the Proposals

a. Background on the LI NET Demonstration

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D prescription drug benefit, which became effective on January 1, 2006. Prior to 2006, beneficiaries who were eligible for both Medicaid and Medicare (dual eligible) received prescription drug benefits through Medicaid. When the MMA went into effect, dual eligible beneficiaries began receiving their prescription drug benefits through Medicare Part D.

From the beginning of Part D, CMS recognized the need to provide both immediate and retroactive coverage for full benefit dual eligible (FBDE) beneficiaries who were newly identified by either CMS or a State. Prior to 2010, CMS automatically enrolled newly identified beneficiaries eligible for the Part D low-income subsidy (LIS) into a Part D plan with a premium at or below the low-income benchmark (''benchmark'' plans), which have no or reduced premiums for LIS-eligible beneficiaries. Each benchmark plan receiving these beneficiaries was required to grant retroactive coverage to the beginning of a beneficiary's LIS-eligible status or their last uncovered month, whichever date was later. At the time, there were around 300 Part D benchmark plans, and each needed to develop the capacity to provide transitional and retroactive coverage for these beneficiaries. Conducting retroactive claims adjudication and providing point-of-sale coverage was not efficient for Part D sponsors and accordingly, in 2010, CMS established the Medicare Part D Demonstration for Retroactive and Point of Sale Coverage for Certain Low-Income Beneficiaries, also known as Medicare's Limited Income Newly Eligible Transition (LI NET demonstration). The LI NET demonstration consolidates administration of transitional and retroactive Part D coverage for eligible beneficiaries to a single Part D sponsor.

Part D coverage under the LI NET demonstration differs from coverage under traditional Part D plans in that the LI NET demonstration provides point-of-sale coverage for beneficiaries who demonstrate an immediate need for prescriptions, and also provides retroactive and/or temporary coverage for beneficiaries determined to be eligible, or likely to be eligible, for the Part D LIS by the Social Security Administration (SSA) or a State. The LI NET demonstration provides temporary, transitional Part D prescription drug coverage for LIS-eligible beneficiaries, including beneficiaries who are eligible for the Part D LIS but who are not yet enrolled in a Part D drug plan, or are enrolled in a plan but for whom coverage has not yet taken effect.

The purposes of the demonstration are to provide the following:

- More efficient prescription drug coverage and claims reimbursement for newly eligible low-income beneficiaries, including periods of retroactive eligibility;
- More efficient prescription drug coverage and claims reimbursement for individuals who are not enrolled in a PDP and whose LIS status is not yet established in CMS' systems, but who arrive at a pharmacy with an immediate need for their prescription. This may occur, for instance, when a State has determined that a beneficiary is eligible for Medicaid but that information does not yet appear in CMS' systems;
- A seamless transition for LIS-eligible beneficiaries from LI NET into a qualifying PDP with basic prescription drug coverage absent a beneficiary's choice otherwise; and
- More efficient prescription drug coverage and claims reimbursement for LIS-eligible beneficiaries who are losing existing coverage in a PDP. For example, a beneficiary could be terminated for moving out of the service area of their current PDP. The beneficiary would be automatically enrolled into LI NET for that month and the following month, with enrollment into a qualifying PDP with basic prescription drug coverage that would become effective at the end of the LI NET enrollment absent the beneficiary's choice otherwise.

b. Introduction to the Proposals To Implement LI NET as a Permanent Program

Division CC, title I, subtitle B, section 118 of the Consolidated Appropriations Act 2021 (CAA) (Pub. L. 116–260) modified section 1860D–14 of the Act by redesignating subsection (e) of section 1860D–14 as subsection (f) and by establishing a new subsection (e) Limited Income Newly Eligible Transition Program. New subsection (e)(1) requires the Secretary to ''carry out a program to provide transitional coverage for covered Part D drugs for LI NET eligible individuals. . .'' no later

than January 1, 2024. This directive in section 118 of the CAA makes LI NET a permanent program within Part D, beginning in 2024.

The proposed rulemaking to establish the LI NET program is consistent with President Biden's Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021) and Executive Order 14085 on Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government (December 13, 2021). LI NET ensures that low-income beneficiaries transitioning from Medicaid to Medicare do not experience a gap in coverage for their prescription medications. Executive Order 14085 calls for the Federal Government to design and deliver services with ''a focus on the actual experience of the people whom it is meant to serve'' and ''deliver services more equitably and effectively, especially for those who have been historically underserved.'' We have designed the proposed LI NET program with beneficiary needs foremost in mind, ensuring continuous drug coverage and access for eligible low-income individuals.

LI NET policies, infrastructure, and operations have evolved over the past 12 years to balance providing needed coverage with responsible stewardship of taxpayer dollars and efficiency in administering the program. The LI NET demonstration has proven successful in providing low-income individuals transitional Part D coverage. Approximately 8 million low-income individuals received the benefits of the LI NET program under the demonstration, with over 100,000 beneficiaries enrolled in LI NET in any given month. It has become a program that beneficiary advocacy groups rely on when supporting low-income individuals and connecting them with services. LI NET works directly with over a dozen advocacy groups and 51 State Health Insurance Assistance Programs (SHIPs), which collectively work with LIS beneficiaries to remove access barriers and provide health insurance counseling.

We believe the LI NET demonstration has become a reliable, stable program that has been successful in providing transitional and retroactive Part D coverage to millions of beneficiaries. In developing our proposals for implementing the permanent LI NET program, we have taken into consideration our experience under the LI NET demonstration. Where appropriate, we discuss the policies and practices under the LI NET demonstration that inform our proposals for how to implement aspects of the LI NET program that are not directly specified by the statute.

We rely on the premise that Part D regulations apply to the LI NET program and to the LI NET sponsor as part of the Part D program and as a type of Part D sponsor, except for when the statute requires us to deviate or when existing regulations would not apply. For example, as discussed further in this proposed rule, because the LI NET sponsor is required to have an open formulary, existing Part D requirements on formulary development would not be applicable.

Our proposals to make LI NET a permanent program start with § 423.2500. In § 423.2500(a), we propose the basis of the LI NET program would be based on section 1860D–14 of the Act. We propose in § 423.2500(b) the scope of the LI NET program, which would begin no later than January 1, 2024. Under this program, eligible individuals would be provided transitional coverage for part D drugs. Section § 423.2504 sets forth the LI NET eligibility and enrollment proposals and § 423.2508 proposes LI NET benefits and beneficiary protections. Next, we propose in § 423.2512 the requirements to be an LI NET sponsor and § 423.2516 proposes how the Part D sponsor administering LI NET in partnership with CMS will be selected and the requirements set forth in the LI NET contract to provide services and coverage. Section 423.2518 provides a proposal for intermediate sanctions in the event of contract violations. Section 423.2520 proposes how an LI NET contract would be non-renewed or terminated. Section 423.2524 lays out our proposals for bidding and determining the LI NET payment rate. Finally, § 423.2536 enumerates the Part D requirements we propose waiving for LI NET.

We propose to align sunsetting the demonstration seamlessly with the start of the LI NET program under this section. Specifically, the LI NET demonstration would continue to operate until December 31, 2023, and the LI NET program would start to operate on January 1, 2024 according to the regulations that we finalize.

2. Eligibility and Enrollment

a. Eligibility

Section 1860D–14(e)(2) of the Act provides that an individual is eligible for LI NET coverage if they: (A) meet the requirements of section 1860D–14(a)(3)(A)(ii) and (iii) of the Act; and (B) have not yet enrolled in a prescription drug plan or an MA–PD plan, or, who have so enrolled, but with respect to whom coverage under such plan has not yet taken effect. This means that to be eligible, the individual would need to be a full-benefit dual-eligible individual or low-income subsidy (LIS) eligible individual as defined at § 423.773 and—

- Not yet be enrolled in a prescription drug plan or an MA–PD plan; or
- Be enrolled but their coverage has not yet taken effect.

Under these requirements, LI NET would be available to all categories of individuals who are LIS-eligible, including:

- Full Subsidy-Full Benefit Dual Eligible (FBDE) individuals, including institutionalized beneficiaries and beneficiaries receiving home and community-based services;
- Full Subsidy-Non-FBDE Individuals, including those who have applied or are eligible for QMB/SLMB/QI or SSI, with income and resource thresholds at or below the amounts set by CMS each year; and
- Partial Subsidy Individuals, including those who have applied and have income and resource amounts below the thresholds set by CMS each year.

We propose to codify at Subpart Y the LI NET eligibility requirements set forth in section 1860D–14(e)(2) of the Act. We propose to establish in paragraph (a) of new § 423.2504 two categories of individuals eligible to enroll in LI NET that encompass the previously noted categories of low-income individuals recognized by Part D. The first category, which we term ''LIS-eligible'' in proposed paragraph (a)(1), would be composed of individuals whose low-income status has been confirmed either through CMS's data in our system of record or because the individual can demonstrate their current or future low-income status. The second category, which we term ''immediate need'' in proposed paragraph (a)(2), would consist of individuals whose low-income status has not been confirmed, because CMS's data do not yet reflect the individual's low-income status, but the individual has indicated that they are eligible for the LIS.

We refer to the individuals in the category established in proposed paragraph (a)(2) as ''immediate need'' because they present at a pharmacy or to the LI NET sponsor in immediate need of a prescription and have no Part D coverage. Ideally, these beneficiaries would be able to show documentation of their pending LIS status, such as a letter received from the State showing the beneficiary's LIS status. However,

we do not believe an absence of documentation in hand at the point-of-sale should be a barrier to entry to LI NET for immediate need individuals. This is because our experience in the demonstration is that 80 percent of immediate need individuals do have their eligibility confirmed,[4] and we would not want to turn away these individuals who imminently require access to their prescription drugs. Under the LI NET demonstration, individuals can indicate the likelihood of their low-income status by providing the evidence they have, which can include verbal explanations of why they consider themselves eligible.

We propose in § 423.2504(a)(2) to grant immediate access to covered Part D drugs at the point-of-sale for individuals whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale. Under proposed paragraph (a)(2)(i), immediate need individuals may provide documentation to the LI NET sponsor to confirm LIS eligibility. Documentation could include, but would not be limited to—

- A copy of the beneficiary's Medicaid card that includes their name and eligibility date;
- A copy of a letter from the State or SSA showing LIS status;
- The date that a verification call was made to the State Medicaid Agency, the name and telephone number of the State staff person who verified the Medicaid period, and the Medicaid eligibility dates confirmed on the call;
- A copy of a State document that confirms active Medicaid status;
- A screen-print from the State's Medicaid systems showing Medicaid status; or
- Evidence at point-of-sale of recent Medicaid billing and payment in the pharmacy's patient profile.

Under proposed paragraph (a)(2)(ii), if an immediate need individual's LIS status cannot be confirmed within a period of 2 months, that individual would not be automatically enrolled into a Part D plan. This is the same as current practice under the LI NET demonstration. We solicit comment on the proposal to align the 2 months of enrollment with the ability to fill prescriptions for these immediate need beneficiaries.

We propose in § 423.2504(a)(2)(i) that immediate need beneficiaries whose eligibility cannot be confirmed can continue to fill prescriptions throughout their 2-month enrollment in LI NET. We believe this ensures access to LI NET benefits and is an administratively simple approach as compared with alternative ideas, such as the approach under the demonstration of keeping immediate need beneficiaries with uncertain eligibility enrolled in LI NET but unable to fill prescriptions. We propose in § 423.2504(a)(2)(ii) that if, by the end of an immediate need individual's enrollment in LI NET, neither CMS's systems nor the beneficiary's provision of documentation confirms low-income status, then that individual would not be auto-enrolled into a qualifying standalone Part D plan following their LI NET coverage.

b. Enrollment

Section 1860D–14(e) of the Act does not specify a process for enrollment into the LI NET program. Therefore, in forming our proposed enrollment process, we look to the process used in the demonstration. Under the LI NET demonstration, there are four ways for eligible individuals to be enrolled into the demonstration. They are as follows:

Automatic enrollment. Individuals who are LIS-eligible but do not yet have Part D coverage, and those individuals who have selected a Part D plan but whose enrollment has not taken effect, are enrolled by CMS into the LI NET demonstration unless the beneficiary has affirmatively declined enrollment in Part D.

Point of sale enrollment. Immediate need individuals whose claims are submitted by the pharmacy at the point-of-sale and billed to LI NET are enrolled into the LI NET demonstration by the LI NET sponsor.

Direct reimbursement request. Individuals who are LIS-eligible and who submit receipts for reimbursement for claims paid out of pocket are retroactively enrolled into the LI NET demonstration by the LI NET sponsor, with 36-month retroactive coverage for full dual eligible individuals and those who receive supplemental security income (SSI) benefits.

LI NET application form. Beneficiaries who are not enrolled into LI NET through auto-enrollment, point-of-sale enrollment or via an approved direct reimbursement request may submit an application form to the LI NET sponsor with supporting documentation demonstrating their LIS status. The LI NET sponsor will periodically check for eligibility and enroll applicants once eligibility is confirmed.

The majority of LI NET beneficiaries are enrolled into the LI NET demonstration automatically by CMS; about 90 to 95 percent of LI NET beneficiaries are those we identify in our systems and enroll into the demonstration. To do this, CMS ''sweeps'' our data monthly to identify all beneficiaries who are—

- Eligible for LIS;
- Eligible for Part D;
- Not enrolled in a Part D plan or receiving the Retiree Drug Subsidy (RDS) or coverage through Veterans Affairs;
- Have not opted-out of Part D enrollment for any reason (for example, because they declined it);
- Not incarcerated, are lawfully present in the US, and do not live in another country; and
- Are not enrolled in a Part C plan that disallows concurrent enrollment in a Part D plan.

Beneficiaries identified in the monthly sweep are automatically enrolled into the LI NET demonstration for that month and the following month. CMS then prospectively enrolls the beneficiary into a traditional Part D plan, with coverage under that plan taking effect immediately after the LI NET coverage ends. This population of beneficiaries includes those who may be gaining Part D eligibility or LIS status but have not made an election into a Part D plan.

A smaller number of beneficiaries, about five to ten percent of LI NET beneficiaries, enroll in the LI NET demonstration outside of the sweeps process. Some enroll at the point-of-sale, as described previously. An even smaller number of beneficiaries contact the LI NET sponsor directly to enroll in the LI NET demonstration. Individuals can submit a request for reimbursement to the LI NET sponsor. If the person is LIS-eligible, the LI NET sponsor enrolls them into the LI NET demonstration and reimburses them for out-of-pocket costs during the duration of their retroactive enrollment. As with an individual who is enrolled at the point-of-sale, the start date of LI NET enrollment would be the first of the month the request is received. There may be individuals who do not have an immediate need for medication and believe they are eligible for LI NET. These individuals can fill out an application form, which allows the LI NET sponsor to periodically check their eligibility and enroll them into LI NET if they become eligible.

Consistent with the enrollment processes under the demonstration, we propose in § 423.2504(b) to codify the ways in which individuals can be enrolled into LI NET: auto-enrollment,

[4] Of the 80 percent of immediate need LI NET beneficiaries whose LIS status is ultimately confirmed, for 89 percent confirmation was within 10 days, and for 97 percent confirmation was within 21 days. In the demonstration, beneficiaries whose LIS status is not able to be confirmed within 21 days continue to be enrolled in LI NET for two months, but they can no longer fill prescriptions after 21 days.

point-of-sale for immediate need individuals, direct reimbursement, and LI NET enrollment form.

In § 423.2504(b)(1), we propose that individuals who are LIS-eligible and whose auto-enrollment into a Part D plan (as outlined in § 423.34(d)(1)) has not taken effect will be automatically enrolled by CMS into the LI NET program unless they have affirmatively declined enrollment in Part D per § 423.34(e). LIS-eligible beneficiaries who have made the decision to opt out of enrollment in Part D must take a proactive step to contact CMS for us to record that decision in our systems by placing a flag on the beneficiary's record. Beneficiaries may opt out of Part D enrollment if they have other insurance or do not want to participate as a matter of principle. We assume that a beneficiary who opts out of Part D enrollment would also want to opt out of transitional coverage under the LI NET program. Therefore, proposed § 423.2504(b)(1) would provide that when a beneficiary affirmatively declines enrollment in Part D per § 423.34(e), that would also entail opting out of LI NET enrollment.

In defining ''transitional coverage'' for LI NET, the statute sets forth requirements for the duration of LI NET coverage under section 1860D–14(e)(3). Section 1860D–14(e)(3)(A) of the Act establishes that ''immediate access to covered part D drugs at the point of sale during the period that begins on the first day of the month such individual is determined to meet the requirements of clauses (ii) and (iii) of subsection (a)(3)(A) and ends on the date that coverage under a prescription drug plan or MA–PD plan takes effect with respect to such individual.'' The starting point of enrollment into LI NET for these types of LIS-eligible beneficiaries, whether they are automatically enrolled or immediate need individuals, is required by statute but the duration of time they prospectively remain enrolled in LI NET is not specified. Under the demonstration, we have typically capped non-retroactive coverage in LI NET to 2 months. Consistent with the statute and with our operations under the demonstration, in § 423.2504(c), we propose that LI NET enrollment begins on the first day of the month an individual is identified as eligible under § 423.2504 and ends after 2 months.

Section 1860D–14(e)(3)(B) of the Act sets a limit on how far back retroactive LI NET coverage can extend. Full-benefit dual eligible individuals (as defined in section 1935(c)(6)) and recipients of supplemental security income (SSI) benefits under title XVI) are eligible for up to 36 months of retroactive coverage. In proposed § 423.2504(c)(2), retroactive LI NET coverage would begin on the date an individual is identified as full-benefit dual or an SSI benefit recipient, or 36 months prior to the date such individual enrolls in (or opts out of) Part D coverage, whichever is later. This duration of time is similar to retroactive coverage under the demonstration, which provides for a maximum retroactive period of 36 months for Full Subsidy LIS eligible individuals.[5] As with LI NET beneficiaries without retroactive coverage, we propose that LI NET coverage would end with enrollment into a Part D plan or opting out of Part D coverage.

We propose in § 423.2504(d) that enrollment in LI NET would end on the date that coverage under Part D takes effect, consistent with section 1860D–14(e)(3) of the Act. In the case of immediate need beneficiaries for whom LIS-eligibility is not confirmed and who are not enrolled into a PDP, enrollment would end 2 months after the immediate need enrollment begins. No matter the method of enrollment, we propose that the minimum duration of LI NET enrollment is 2 months unless the beneficiary elects to disenroll from LI NET or to enroll in a Part D plan. For example, an individual whom we auto-assign into LI NET starting April 1, 2024 would remain in LI NET for April and May 2024 before being enrolled into an appropriate Part D plan starting June 1, 2024.

We provide two beneficiary examples to further explain how LI NET enrollment and disenrollment would work under our proposals:

Example 1: Beneficiary Kristy is a full-benefit dual eligible and arrives at a pharmacy on May 5, 2024, with documentation showing that her LIS application is pending. She would have immediate coverage in LI NET for May and June 2024. If, in the course of adjudicating her LIS application, it is discovered that she was actually LIS-eligible dating back to January 2016, Kristy would be retroactively enrolled in LI NET as of July 1, 2021, which is the later of 36 months prior to the date she is enrolled in a Part D plan or the date she was first LIS eligible (since January 2016 is more than 36 months prior to her Part D plan enrollment, her retroactive coverage under LI NET is capped at 36 months prior to such enrollment). Kristy's LI NET coverage would end June 30, 2024, upon her enrollment into a benchmark PDP starting July 1, 2024, unless she makes the choice to opt-out.

Example 2: The Social Security Administration notifies CMS in February 2024 that Beneficiary Ravi was eligible for both Medicare and SSI starting in November 2022. CMS provides Ravi retroactive Medicare drug coverage from November 2022, which is the later of 36 months prior to enrollment in a Part D plan or the date Ravi was first LIS eligible, through March 2024. After March 2024, if Ravi does not actively enroll in a plan of their choosing, CMS would randomly enroll them into a benchmark PDP with an April 1, 2024 effective date.

As noted previously, our goal in the proposals is to match current eligibility and enrollment policy in effect in the demonstration and the Part D program, to the extent the statute permits. We seek comment on whether revised or additional regulations are required to achieve accurate, streamlined, and beneficiary friendly eligibility determinations and enrollment in the LI NET program.

3. Benefits and Beneficiary Protections

Section 1860D–14(e)(4)(B)(i) of the Act requires the LI NET program to provide eligible beneficiaries with access to all Part D drugs under an open formulary. The statute, at clauses (ii) and (iii) of section 1860D–14(e)(4)(B) of the Act, also requires the LI NET program to permit all pharmacies that are determined by the Secretary to be in good standing to process claims under the program, and to be consistent with such requirements as the Secretary considers necessary to improve patient safety and ensure appropriate dispensing of medication. These requirements are consistent with how the LI NET demonstration has operated, and we propose to codify the requirement that the LI NET program provide access to all Part D drugs under an open formulary in § 423.2508(a). We propose in § 423.2508(b) to require the LI NET sponsor to permit all pharmacies that CMS determines to be in good standing to process claims under the program, whether or not the pharmacy is a network or out-of-network (OON) pharmacy for the LI NET sponsor. Under the demonstration, we consider a pharmacy, including retail, mail-order, and institutional pharmacies, to be ''in good standing'' when it is licensed and does not have a fraud, waste, or abuse

[5] The LI NET demonstration provides an exception to the 36-month maximum period of retroactive enrollment if there is a Medicaid determination within the last 90 days that confers Medicaid eligibility going back further than 36 months. In these situations, LI NET enrollment under the demonstration goes back to the start of Medicaid eligibility. We are not proposing an exception to the 36-month limit on retroactive coverage in this rulemaking as the statute does not provide for such an exception.

determination against it. For the permanent LI NET program, we propose that a pharmacy would be in good standing if it is licensed, has not been revoked from Medicare under § 424.535, does not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs pursuant to section 1128 of the Act and from Medicare under section 1156 of the Act (unless the OIG waives the exclusion, which the OIG has authority to do in certain specified circumstances), and does not appear on the preclusion list as defined in § 423.100. A pharmacy will appear on the preclusion list if it:

- Is currently revoked from Medicare, is under an active reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program, including LI NET;
- Has engaged in behavior for which CMS could have revoked the entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program, including LI NET; or
- Has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program, including LI NET.

In § 423.2508(c), we propose requirements we consider necessary to improve patient safety and ensure appropriate dispensing of medication consistent with subpart D of the Part D regulations. Existing Part D requirements related to appropriate dispensing, patient safety, electronic dispensing, quality improvement organization (QIO) activities, compliance, and accreditation would improve patient safety and appropriate dispensing. Specifically, we propose to apply the following provisions to the LI NET program and LI NET sponsor, as appropriate:

- § 423.153(b) and (c) for dispensing and point-of-sale safety edits.
- § 423.154 for appropriate dispensing of prescription drugs in long-term care facilities.
- § 423.159, requiring an electronic prescription drug program.
- § 423.160, excepting the requirements pertaining to formulary standards in § 423.160(b)(5), setting forth standards for electronic prescribing.
- § 423.162, for quality improvement organization (QIO) activities.
- § 423.165, regarding compliance deemed on the basis of accreditation.

We solicit comment on whether any of these provisions would not be compatible with the LI NET program proposed in this rulemaking.

Section 1860D–14(e)(4)(B)(iv) of the Act provides the Secretary the authority to establish requirements for the LI NET coverage provided to LI NET eligible individuals. We draw upon our experience under the demonstration to propose cost sharing and appeals policy for LI NET in sections § 423.2508(d) and (e), respectively.

We propose in § 423.2508(d)(1) that LI NET beneficiaries under § 423.2504(a)(1) (that is, beneficiaries whose LIS-eligibility is established and who have not yet enrolled in a prescription drug plan or MA–PD plan, or who have enrolled in a prescription drug or MA–PD plan but coverage under such plan has not yet taken effect) would pay the applicable cost sharing for their low-income category as established in the yearly Announcement of Calendar Year Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Rate Announcement publication specified in § 422.312). Under the demonstration, LI NET beneficiaries pay the reduced cost-sharing aligned with the LIS categories defined in the Part D program. Because there is already the existing statutory requirement for CMS to update the parameters for the LIS benefit each year using statutory indexing methods, and because CMS and pharmacy systems are already set up to reflect the appropriate cost-sharing based on the LIS category of the individual, we believe it is reasonable to calculate and charge cost-sharing in alignment with the Part D LIS categories. For immediate need beneficiaries, we propose in § 423.2508(d)(2) these individuals would by default pay the cost-sharing associated with the category of non-institutionalized FBDE individuals with incomes above 100 percent of the Federal poverty level and full-subsidy-non-FBDE individuals (that is, Category Code 1). Of the four LIS eligibility categories, this category has the highest level of cost-sharing. Proposed § 423.2508(d)(2) would further provide that if the beneficiary is later confirmed to belong to a different LIS category, the beneficiary would be refunded by the LI NET sponsor for the difference between the cost sharing they paid versus what they would have paid in their confirmed LIS category. This approach allows for the least government liability for individuals whose LIS eligibility is unable to be confirmed while still allowing prescription drug access for immediate need individuals.

We propose in § 423.2508(e) that LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of the Part D regulations. The established processes would adequately adjudicate LI NET beneficiary concerns. This approach of using existing processes avoids needing to devote resources to establishing separate grievance, coverage determinations. Furthermore, consistency with other Part D contracts as it relates to grievances, coverage determinations, and appeals would be simplest for LI NET sponsors.

4. LI NET Sponsor Requirements

Section 1860D–14(e)(4)(A) of the Act specifies that, as determined appropriate by the Secretary, the LI NET program is to be administered through a contract with a single administrator. Since the beginning of the demonstration, CMS has had one Part D sponsor serve as the sole contractor for administering the program. We have found that this approach supports our goal of administrative simplicity by making it unnecessary for each individual plan sponsor to check eligibility and conduct a retroactive enrollment/reimbursement process. In our experience, the benefits of having a single Part D sponsor administer LI NET include the following:

- Providing a single point of contact for beneficiaries and pharmacies attempting to have their claims paid.
- Providing a single point of contact for State Medicaid agencies submitting Medicaid eligibility and attempting to reconcile and coordinate claims.
- Simplifying the filing of retroactive beneficiary claims.

There may be circumstances in which CMS may want to consider contracting with more than one Part D sponsor to administer LI NET. Though we have had stability in LI NET in terms of only having the single LI NET sponsor for the duration of the demonstration, we recognize the need for some protections should it become necessary for another entity to take over as LI NET sponsor and assume responsibility for providing LI NET coverage. The downside of consolidating LI NET functions into a single sponsor is the potential for beneficiary impact should there be a reason that the single LI NET sponsor no longer continues its functions. We believe that this potential of beneficiary impact is mitigated by our proposals to non-renew or terminate the LI NET contract, which are discussed in greater detail in section II.D.5. of this proposed rule, titled ''Contractor Selection and Contracting Guidelines.'' Accordingly,

while we propose at new § 423.2512 that the program will be operated by ''one or more'' Part D sponsors, we intend to initially continue with the current practice of operating the program through a single sponsor because we determined the benefits outweigh potential beneficiary impacts, which have not come to bear since the start of the demonstration in 2010.

We propose to establish at § 423.2512 the requirements the LI NET sponsor must meet when administering the LI NET program.

- Because LI NET may enroll beneficiaries from across the nation, we propose to specify at § 423.2512(a)(1) that the LI NET sponsor(s) would be selected from among the Part D sponsors with a national presence, with an established contracted pharmacy network in all geographic areas of the United States in which LIS is available, which as of the date of this proposed rule is the 50 States and the District of Columbia. Because LIS is not available in the territories, CMS would not require the LI NET sponsor to have network pharmacies in territories. LI NET beneficiaries could still access LI NET benefits while in the territories if needed, however, through out-of-network pharmacies.
- We find that some experience as a Part D sponsor should be a pre-requisite for being an LI NET sponsor, and propose at § 423.2512(b) that any candidates to be an LI NET sponsor have a minimum of 2 consecutive years contracting with CMS as a Part D sponsor.
- We propose at § 423.2512(c) some technical and operational requirements of the LI NET sponsor. In § 423.2512(c)(1) and (c)(2) we propose that the LI NET sponsor have the technical capability and the infrastructure to provide immediate, current, and retroactive coverage for LI NET enrollees and the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible LI NET enrollees. In § 423.2512(c)(3), we propose requiring the LI NET sponsor to identify, develop, and implement outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program. Under the demonstration, CMS enrolls over 90 percent of LI NET beneficiaries into the LI NET plan and we expect CMS would continue to be responsible for most enrollees in a permanent LI NET program. For the beneficiaries who are not auto-enrolled, outreach is important so that stakeholders like the states, SHIPs, and pharmacies to have awareness and knowledge about the LI NET program. Under the demonstration, the LI NET sponsor routinely conducts outreach in consultation with CMS to inform stakeholders about the program. We propose to adopt this approach for the permanent LI NET program.

As discussed further in this section of this rule, we propose to waive requirements under §§ 423.128(d)(2)(ii), 423.128(d)(2)(iii), and 423.128(d)(4). We also propose in § 423.2512(c)(4) that the LI NET sponsor be required to establish and manage a toll-free customer service telephone line and fax line that can be accessed by pharmacy providers and beneficiaries, or others acting on their behalf, for purposes that include but are not limited to: handling inquiries about services under the LI NET program, providing the status of eligibility or claims, and having the ability to accept documentation for evidence of eligibility.

Reimbursement to beneficiaries with retroactive coverage is provided for in section 1860D–14(e)(3)(B) of the Act, as the ''amounts that would have been paid under this Part had such individual been enrolled in a prescription drug plan or MA–PD plan.'' This entails establishing a process for beneficiaries to request and receive such reimbursement. In the demonstration we provide a means for beneficiaries who receive retroactive coverage to submit a direct member out-of-pocket reimbursement request for Part D covered drugs for any past month(s) in which they were entitled to retroactive coverage under LI NET. The LI NET sponsor provides reimbursement to eligible beneficiaries based on the submitted cost minus any applicable copayments. Once the LI NET sponsor receives a written reimbursement request, they follow timeframes that are consistent with those Part D sponsors are already accustomed to in § 423.636(a)(2) when they authorize payment for a benefit due to a reversal in their coverage determination. That is, under the demonstration, the LI NET sponsor has 14 calendar days to reply with whether the claim is eligible for reimbursement, including the reason for denying the request if applicable. If the request for reimbursement is granted, the LI NET sponsor issues the reimbursement no later than 30 days after it determines the claim is eligible for reimbursement. As these timelines have proved workable under the demonstration, we propose in § 423.2512(c)(5) that the LI NET sponsor meet these deadlines related to direct reimbursement in the permanent LI NET program.

In § 423.2512(c)(6), we propose requiring the LI NET sponsor to adjudicate claims from out-of-network pharmacies according to the LI NET sponsor's standard reimbursement for their network pharmacies. As the LI NET sponsor must provide access to all Part D drugs under an open formulary, we believe there is the need for some protection against unreasonably high drug costs for OON claims in LI NET. Other Part D sponsors have the option to deny such claims, or to pay OON claims according to their standard reimbursement for their network pharmacies (with beneficiaries paying any difference between the cost of the OON claim the negotiated price). Because this restraint on unreasonable drug costs borne by the Medicare Trust Funds would not otherwise be present for LI NET, we believe a limit on how much the LI NET sponsor can be reimbursed for OON claims is needed.

5. Selection of LI NET Sponsor and Contracting Provisions

Section 1860D–14(e)(6) of the Act authorizes us to implement LI NET without regard to laws relating to the making, performance, amendment, or modification of contracts of the United States as we may determine to be inconsistent with the furtherance of the purpose of Title XVIII. Thus, CMS is not required to follow the Federal Acquisition Regulation (FAR) or the contracting authority used under the Part D program. Neither is CMS required to contract with every qualified plan sponsor to provide LI NET Part D coverage, as we are required to do for qualified plan sponsors providing non-LI NET Part D coverage. If we followed the same approach for LI NET, we could have many points of contact for beneficiaries and pharmacies attempting to have their retroactive claims paid and multiple points of contact for State Medicaid agencies submitting Medicaid eligibility and attempting to reconcile and coordinate claims. This approach would not serve the purpose of providing smooth, transitional coverage for Part D drugs for LI NET eligible individuals through the LI NET program, which is a Part D program under Medicare in Title XVIII.

Using the authority in section 1860D–14(e)(6) of the Act, we propose to follow the contracting approach set forth in proposed § 423.2516 to select the LI NET sponsor for the 2024 plan year and onwards.

In § 423.2516(a), we propose that CMS would appoint a Part D sponsor that meets the requirements at § 423.2512 to serve as the LI NET sponsor. To determine this appointment, we propose that CMS may choose to conduct discussions with potentially eligible

entities to establish mutual interest and ability to administer the program. This circumstance could arise if, for example, CMS needs additional information in any particular year to learn more about a Part D sponsor's ability to administer the LI NET program. Under the demonstration, there is a multi-year contract approved by the Office of Management and Budget, and each year CMS and the LI NET sponsor have executed an addendum to the contract that included such information as the payment rates and risk corridors as determined in the final bid. As we consider options for establishing regulations to implement the permanent LI NET program, we find it is appropriate that we bring the LI NET contractor into closer alignment with other contracts in the Part D program by executing an LI NET contract with a Part D plan sponsor each plan year that contains, among other information, payment information for that year. Our expectation is that unless circumstances shift to prompt a change, the existing LI NET sponsor would continue in that role in the succeeding year. Therefore, in § 423.2516(b), we propose selection criteria CMS may use in appointing an LI NET sponsor based on some features of the LI NET program that are related to a Part D sponsor's ability to successfully administer the program. These are—

- Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in § 423.34;
- Pharmacy access as outlined in § 423.120;
- Past performance consistent with § 423.503(b), including Star Ratings (as detailed in § 423.186), and previous intermediate sanctions (as detailed in § 423.750); and
- Ability to meet the requirements listed in § 423.505 that are not waived under § 423.2536.

As we are proposing that Part D requirements apply to the LI NET program unless waived, we intend for § 423.505 to apply to LI NET, with the exception of § 423.505(k)(6), which we propose to waive in proposed § 423.2536(g). For example, the contract between the LI NET sponsor and CMS would be required to contain provisions in which the LI NET sponsor agrees to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments (see § 423.505(a) and (b)(2)). As another example, consistent with § 423.505(b)(22), the LI NET contract would be required to include a provision in which the LI NET sponsor agrees to use the CMS complaint tracking system to address and resolve complaints received by CMS against the sponsor. Per § 423.505(k), the LI NET contract would also require the LI NET sponsor to submit certifications of data that determine payment as applicable, such as for enrollment and payment information, claims data, bid submission information, DIR data, and overpayments. The only certification the LI NET sponsor would not submit is the one pertaining to data for price comparison under § 423.505(k)(6); we believe this certification is unnecessary given that the LI NET plan is not one for which beneficiaries shop and thus would not be comparing against other plan options based on price considerations. We intend to exclude LI NET from Medicare Plan Finder, consistent with past practice under the demonstration. Therefore, it would not make sense to require certification to data for price comparison purposes, and we propose to waive this requirement in § 423.2536(g).

In § 423.2516(c), we propose that the term of the appointment will be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per proposed § 423.2524(c)) to determine payment rates for the upcoming year. This approach has worked well during the demonstration and we see no reason to propose a different approach for the permanent program.

If the LI NET sponsor violates its contract, we propose in § 423.2518 that CMS would have the authority to impose intermediate sanctions as outlined in subpart O of the Part D regulations, just as we would for any other Part D sponsor.

In § 423.2520(a) we propose that if the LI NET sponsor decides for any reason to non-renew its existing contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS would notify the LI NET sponsor by January 1 of the year before the next contract year. We propose that CMS could non-renew for any reason, without cause, and the LI NET sponsor would not have a right to appeal the non-renewal. To provide CMS the authority to non-renew the LI NET contract with that particular sponsor for any reason with no appeal, we propose in § 423.2536(e) waiving the appeals requirements in Subpart N except for those relevant to a contract termination. As there has only been a single LI NET sponsor for the duration of the demonstration, and we are anticipating a single LI NET sponsor for the permanent LI NET program, we do not want to assume the risk of the appeals process not providing finality by the time an LI NET sponsor would need to begin preparing the LI NET bid. Even if we required the appeals process to be complete by the April timeframe and while the appeal was pending moved forward with selection process, we would be cutting into or needing to forgo entirely the transition time of 3 months we propose in § 423.2520(b) to ensure seamless transition of the LI NET program. Proposing to assume these risks would not further the purpose of the LI NET program being ready and available to provide immediate, current, and retroactive coverage for LI NET enrollees. We note that non-renewal, whether at the election of CMS or the LI NET sponsor, would not have an impact on the sponsor's eligibility to be selected as the LI NET sponsor in future years. As discussed in section II.D.4. of this proposed rule, we intend to initially contract with a single Part D sponsor to administer the LI NET program. Unlike beneficiaries in traditional Part D plans, beneficiaries enrolled in LI NET would not have the option of simply choosing to enroll in LI NET under a different sponsor. For these reasons, ample notice is needed if the LI NET sponsor does not intend to continue as the LI NET sponsor in the following year. We anticipate that CMS would be able to provide the same amount of notice to the LI NET sponsor if we were contemplating changing the LI NET sponsor for the following year. A decision to non-renew the LI NET contract with a particular Part D sponsor would not bar or prohibit that sponsor from being considered to be the LI NET sponsor in a future year. Any CMS decisions regarding LI NET sponsor selection would have no bearing on a Part D sponsor proceeding with the application process for other, non-LI NET, Medicare prescription drug plans.

In § 423.2520(b), we propose that after a notice of non-renewal, CMS would select a successor LI NET sponsor from among the other eligible entities (as detailed in proposed § 423.2516). Similar to how our multi-year contracts with our contractors require an outgoing contractor to coordinate with any successor contractor during a transition period, proposed § 423.2520(b) would require the outgoing LI NET sponsor to coordinate with the successor LI NET sponsor appointed by CMS for a period of no less than 3 months to ensure seamless transition for LI NET enrollees,

including timely transfer of any data or files. All data, files, written materials, and LI NET work products would be considered CMS's property. During the transition period, the outgoing and incoming LI NET sponsors would work together to develop a transition plan, including setting up a training schedule and a schedule of events for a smooth changeover.

There may be exigent circumstances of risk to beneficiaries in which a more immediate termination is warranted. Referencing portions of CMS's immediate termination authority in § 423.509, we propose to establish in § 423.2520(c) that CMS may terminate the LI NET contract immediately if:

- CMS determinates that a delay in termination, resulting from non-compliance with the procedures provided in this Part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the LI NET sponsor, per § 423.509(b)(2)(i)(A);
- The LI NET sponsor has experienced financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to beneficiary health, or otherwise fails to make services available to the extent that such a risk to health exists per § 423.509(b)(2)(i)(B); or
- The LI NET sponsor has had one or more of the issues enumerated in paragraphs (a)(4)(i) and (xii) of § 423.509.

Proposed § 423.2520(d) would provide that if CMS intends to terminate the contract under proposed § 423.2520(c), CMS provides written notice to the LI NET sponsor informing it of its termination appeal rights in accordance with subpart N of this Part.

We expect to identify the LI NET contract as X0001, and advance the plan benefit package number by one each year so that we can update the payment rates in our systems for the new payment year. If the LI NET contract with a particular LI NET sponsor is terminated, we would not discontinue use of the contract number X0001. Instead, we would terminate the relationship with that specific LI NET sponsor to provide LI NET coverage, and continue to allow enrollment under contract X0001.

6. Bidding and Payments to the LI NET Sponsor

Section 1860D–14(e) of the Act does not specify how CMS is to determine the amounts that it pays to the LI NET sponsor under the contract or how payments are to be made. We propose to establish the methodology and formulas that we would use to determine the amounts we pay to the LI NET sponsor under the contract. We use our payment policies under the demonstration, including the bidding requirements, as the basis for the proposed LI NET payment policies in this rule. We do so because LI NET payment activities bear many similarities to those of typical Part D plans, because the infrastructure to pay in this manner is already established, and because we are proposing that the LI NET sponsor must be a Part D sponsor who would be familiar with these payment activities already, in this proposed rule.

We propose in § 423.2524(a) that CMS payments for the LI NET program would be made from the Medicare Prescription Drug Account, as payments are made to other Part D sponsors.

In § 423.2524(b) we propose requirements related to the LI NET bid. Because most of the provisions in Subpart F would not be applicable to LI NET, we propose to waive Subpart F except for those provisions we propose to apply to LI NET.

Section 423.2524(b)(1) proposes that the submission of LI NET bids and related information will follow the requirements and limitations in Part 423, Subpart F, §§ 423.265(b), (c), (d)(1), (d)(2)(i), (d)(2)(ii), (d)(2)(iv), (d)(2)(v), (d)(4), (d)(6), and (e). This proposal would require the LI NET sponsor to submit a bid and supplemental information in a format specified by CMS, with the same deadline as other Part D bids of no later than the first Monday of June each year. It also gives CMS the ability to request additional information from the LI NET sponsor to support bid amounts, and the ability to require revisions to the submitted LI NET bid before it is accepted. As with other Part D bids, a qualified actuary, whether internal or external to the plan sponsor, would certify the LI NET sponsor's actuarial valuation (which may be prepared by others under the qualified actuary's direction or review). The qualified actuary would need to be a member of the American Academy of Actuaries.

We propose in § 423.2524(b)(2) that the following provisions would apply in the review, negotiation, and approval of the LI NET bid: § 423.272(a), (b)(1), and (b)(4). This would allow CMS to review the LI NET bid, conduct negotiations regarding the terms and conditions of the proposed bid, and approve it only if the bidding LI NET sponsor and the LI NET plan comply with all applicable CMS Part D requirements. As in typical Part D bid reviews, CMS would be able to decline the LI NET bid if it proposes significant increases in cost sharing (§ 423.272(b)(4)). This approach follows the bid process under the demonstration, in which the LI NET sponsor submits a bid that estimates their costs and includes assumptions for enrollment and utilization based on prior experience. Starting with PY2021, the LI NET sponsor began using an LI NET Bid Pricing Tool (BPT) and accompanying instructions that were adapted from the traditional Part D BPT and instructions. Once the LI NET bid is accepted, we update this information in our systems for the new payment year for the LI NET demonstration. Each year, we advance by one the number designating the current plan benefit package. For example, the contract-PBP was X0001–011 for plan year 2021 and X0001–012 for plan year 2022.

Proposed § 423.2524(b)(3) specifies the basic rule and major components of the LI NET bid, which are the LI NET sponsor's estimate of its revenue needs for Payment Rates A and B, which are discussed in greater detail in proposing § 423.2524(d).

In § 423.2524(c) we propose that CMS would provide advance monthly LI NET payments, on a per-member, per-month (PMPM) basis, equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid submitted annually under paragraph (b) of this proposed section. Paying on a PMPM basis would align with other Part D payments and with our operations under the LI NET demonstration in which we provide a capitated PMPM amount established by the bid for each beneficiary enrolled in the demonstration. Unlike typical Part D monthly payments, the monthly LI NET payment under the demonstration is a PMPM amount that represents the sum of Payment Rates A and B, as determined by the LI NET bid. The bid represents the LI NET sponsor's total expected cost, minus any beneficiary co-pays, and with a reasonable margin that represents the LI NET sponsor's profit. Also, unlike other Part D payments, payments under the LI NET demonstration would not be risk adjusted. Because payments under the LI NET demonstration are cost reconciled (with the exception of risk corridors) and there is no concern about the LI NET sponsor cherry-picking beneficiaries, we use a simpler payment methodology that does not include risk adjustment.

We propose in § 423.2524(c)(1) that Payment Rate A would be a monthly payment for projected administrative costs, constrained by an annual percentage cap set as part of the bid

review and negotiation under § 423.272(a). Payment Rate A would include two elements, as it does under the demonstration. The first would be the LI NET sponsor's estimated administrative costs, which would represent the administrative costs to run the LI NET program inclusive of an amount for the margin, which represents the LI NET sponsor's profit. The second element in Payment Rate A would be the LI NET sponsor's estimated costs to pay pharmacy claims for prescriptions filled by immediate need individuals, for which the LI NET sponsor may not be able to submit a prescription drug event (PDE) record to CMS due to the individual's unconfirmed LIS status. We expect that these are generally the ''immediate need'' beneficiaries discussed in section II.D.2.a. of this proposed rule (under the heading ''Eligibility and Enrollment'') who are not confirmed to be LIS-eligible. We propose in § 423.2524(c)(1)(i) that for the 2024 plan year, the LI NET sponsor includes in its bid the assumption that Payment Rate A cannot exceed a 2 percent increase from the prior year's Payment A, which is a figure CMS will provide to the LI NET sponsor. For the 2025 plan going forward, we propose in § 423.2524(c)(1)(ii) the LI NET sponsor will specify their assumption for any increase needed to the prior year's Payment Rate A, submitting justification to CMS in its bid if the cap exceeds 2 percent. Any proposed increase in Payment Rate A from year-to-year would not be able to exceed the percentage cap. Similar to how CMS determines reasonableness in evaluating a plan's anticipated profit in the bid, we would use the same reasonableness standard in setting and negotiating the cap on Payment Rate A in the bid.

In § 423.2524(c)(2), we propose that Payment Rate B would reflect the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit. Payment Rate B would be the estimated actual drug costs minus direct and indirect remuneration (DIR). In the demonstration, we apply risk corridors to Payment Rate B so that excess gains and losses are shared between CMS and the LI NET sponsor. These risk corridors are symmetrical in sharing upside and downside risk, but are narrower than the risk corridors provided for under section 1860D–15(e) of the Act and applicable to other Part D plans. Because the risk corridors in the demonstration are so narrow, the LI NET sponsor has not assumed as much risk for LI NET as traditional Part D plans assume. CMS has not shared risk on Payment Rate A, in keeping with typical Part D plans for which CMS does not share risk on margin or administrative costs. In 2012, CMS revised the risk corridors under the LI NET demonstration to limit payment adjustments on Payment Rate B. For the portion of a plan's cost for drugs that is between the target amount and the threshold upper limit (101 percent of the target amount), the LI NET sponsor pays 100 percent of this amount. For the portion of the plan's cost for drugs that exceeds the threshold upper limit, the government pays 99.9 percent and the plan pays 0.1 percent. Similarly, if a plan's cost for drugs is between the target amount and the threshold lower limit (99 percent of the target amount), the LI NET sponsor keeps 100 percent of the difference between the drug cost and the target amount. If a plan's cost for drugs is lower than the threshold lower limit, the government keeps 99.9 percent and the plan keeps 0.1 percent of the difference between the plan's drug cost and the threshold lower limit.

Both under the demonstration and for other Part D plans, after a payment year is over and the deadline for submitting payment data for that payment year has passed, we reconcile the payments for the year. This allows us to narrow the gap between what predicted and actual costs were in a given year, as well as share risk with plan sponsor in gains and losses. To provide for payment reconciliation and risk sharing in the LI NET program, we propose in § 423.2524(d) to establish the payment policies for reconciliation and risk corridors, including adopting targeted provisions of existing risk sharing requirements. Proposed § 423.2524(d)(1) provides that CMS would conduct LI NET payment reconciliation each year for Payment Rates A and B after the annual PDE data submission deadline has passed and make the resulting payment adjustment consistent with § 423.343(a).

In § 423.2524(d)(2), we propose to establish the same risk corridors for Payment Rate B that apply under the demonstration: no risk sharing within 1 percent of the target amount and symmetrical 0.1 percent risk sharing beyond the 1 percent corridor. To carry out risk sharing as part of reconciliation, we propose to have § 423.336(c) apply to LI NET, which requires a plan sponsor to provide necessary cost data information to CMS and authorizes CMS to make either lump-sum payments or adjustments based on the risk corridor calculations.

Proposed § 423.2524(e) would establish that the LI NET contract is subject to the existing provision at § 423.346 pertaining to payment reopenings. Per § 423.346, CMS may reopen and revise an initial or reconsidered final payment determination for up to 5 payment years. Under the demonstration, each LI NET reconciliation has been in alignment with § 423.346 and included the prior 5 years of PDEs. The most recently completed payment year gets reconciled for the first time along with reopening the prior 4 years. For example, in 2019, PBP 008 for payment year 2018 was reconciled for the first time while PBPs 004–007 (for payment years 2014 through 2017) were reopened. Sequestration is not used or accounted for in reconciliation, consistent with how we apply sequestration for other Part D plans. Under the demonstration, we maintain consistency between LI NET's PDE and DIR reporting deadlines and the reporting deadlines that apply to Part D plans (for example, the yearly deadline for data used for payment year reconciliation is June 30th). Enrollment, risk adjustment, and PDE certifications (attestations) are collected under the LI NET demonstration just like other contracts, and we propose to adopt the requirements in § 423.505(k)(1) through (5), except for certifying to reinsurance data because LI NET does not receive a reinsurance subsidy. This proposal would require the LI NET sponsor to certify to the accuracy, completeness, and truthfulness of all data related to payment.

As noted earlier in this section of this proposed rule, as a general matter, all payment rights and responsibilities under Part D that otherwise apply and are not explicitly waived in proposed § 423.2536 would apply to the LI NET program, as appropriate. Proposed § 423.2524(f) would provide that the LI NET sponsor could appeal the payment calculation under § 423.350. Proposed § 423.2524(g) would establish that the LI NET contractor is subject to the ''report and return'' overpayment requirements under § 423.360.

7. Part D Program Waivers

Because the LI NET sponsor is a Part D sponsor and the LI NET contract is a PDP contract, many existing provisions in Part 423 apply to LI NET. The exceptions are those provisions waived by the statute, those provisions that are inapplicable to LI NET, and the requirements we propose to waive through this rulemaking.

The LI NET statute at section 1860D–14(e)(5)(A) of the Act provides that paragraphs (1) and (3)(B) of section 1860D–4(a) of the Act, subparagraphs

(A) and (B) of section 1860D–4(b)(3) of the Act, and paragraphs (1)(C) and (2) of section 1860D–4(c) of the Act do not apply to the LI NET program; thus, requirements relating to dissemination of general information and the provision of formulary information, formulary requirements, and medication therapy management (MTM) program requirements do not apply to LI NET. For this reason, we propose to waive formulary requirements in §§ 423.120(b), 423.128(e)(5), and 423.128(e)(6) and MTM program requirements in § 423.153.

Section 1860D–14(e)(5)(B) of the Act contains broad waiver authority to ''waive such other requirements of title XI and this title as may be necessary to carry out the purposes of the program established under this subsection''. We also propose to waive for LI NET some of the cost control and quality improvement requirements in Part 423 Subpart D, except for the provisions we explicitly propose to adopt in § 423.2508(d)(1) through (d)(5) that relate to appropriate dispensing, patient safety, electronic dispensing, QIO activities, compliance, and accreditation. This proposal would waive requirements that would not make sense in the context of temporary coverage with access to an open formulary. The requirements we propose to waive pertain to drug utilization management programs, medication therapy management programs, and consumer satisfaction surveys.

We solicit comment on whether we should waive any additional regulatory provisions related to paragraphs (1) and (3)(B) of section 1860D–4(a) of the Act and subparagraphs (A) and (B) of section 1860D–4(b)(3) of the Act.

As discussed in section II.D.4. of this proposed rule, we are proposing that the LI NET sponsor submit most of the certifications listed in § 423.505(k), with the exception that we are waiving the certification of accuracy of data for price comparison in paragraph (k)(6), given that the LI NET plan is not one for which beneficiaries shop.

Part D beneficiaries receiving a low-income subsidy are not eligible for the coverage gap discount program, and under the demonstration LI NET was not subject to coverage gap discount requirements under subpart W of Part 423. Thus, we propose in § 423.2536(i) to waive subpart W in full for LI NET.

We propose in § 423.2536(j) to waive the MLR requirements in subpart X of Part 423.

Section 1857 as incorporated into 1860D–14(e) of the Act does not speak to MLR requirements for LI NET. Under the LI NET demonstration, CMS does not require the LI NET sponsor to meet the minimum medical loss ratio (MLR) requirement or to report the MLR for the LI NET contract as it does for other Part D contracts. This is due to the unique payment structure for the contract. Under Part D, a sponsor submits a single bid including estimated administrative costs, returns on investment, and drug costs, which are risk-adjusted. After a payment year concludes, Part D sponsors are required under subpart X of Part 423 to report the MLR for each contract, and if the MLR for a contract is below 85 percent, the sponsor is required to remit payment to CMS. Enrollment sanctions are applied to contracts that fail to meet the minimum MLR requirement for three3 consecutive years, and contracts that fail to meet the requirement for 5 consecutive years are subject to termination. The minimum MLR requirement is intended to create incentives for Part D sponsors to reduce administrative costs such as marketing costs, profits, and other such uses of plan revenues, and to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. Because of the limits we are proposing to place on how much administrative costs in LI NET under Payment Rate A can increase year over year and because of the differing payment structure, we do not believe MLR reporting should be applicable to LI NET.

The Affordable Care Act amended section 1893(h) of the Act to expand the use of Recovery Audit Contractors (RACs) to include the MA and Part D programs. Section 1893(h)(9) of the Act specifies that, under contracts with the Secretary, Part D RACs are required to ensure that each PDP has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan, to examine claims for reinsurance payments to determine whether PDPs submitting such claims incurred costs in excess of the costs allowed, and to review estimates submitted by PDPs with respect to the enrollment of high-cost beneficiaries and compare such estimates with the numbers of such beneficiaries actually enrolled by such plans. Because the LI NET sponsor must enroll every eligible LI NET beneficiary, and because LI NET does not receive reinsurance, a Part D RAC's review or examination of LI NET claims would likely be extremely limited in scope. As other audit, oversight, and compliance requirements would continue to apply to the LI NET program, the other program integrity safeguards we have proposed for the LI NET program would be adequate, and we therefore propose to waive application of the RAC requirements in subpart Z of Part 423.

In surveying the items under Part 423 for the Voluntary Medicare Prescription Drug Benefit, we attempted to categorize existing requirements as applicable, inapplicable, or a candidate for waiver. We solicit comment on whether there are additional provisions in part 423 that we have not mentioned in this proposed rule and that we should address for LI NET.

8. Technical Corrections

In the course of this rulemaking, we noticed the need for a technical correction in § 423.505(b)(22), which requires Part D sponsors to address and resolve complaints received by CMS against the Part D sponsor. The regulation text currently refers to MA organization when it should refer to Part D sponsor, and thus we propose to make the correction.

We also propose to make a technical correction in the header of subpart Z of Part 423. The header in regulation text currently is ''Recovery Audit Contractor Part C Appeals Process'' when it should be referring to Part D. Thus, we propose to make the technical correction so the header correctly reads, ''Recovery Audit Contractor Part D Appeals Process.''

E. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)

The Part D low income subsidy (LIS) helps people with Medicare who meet certain statutory income and resource criteria pay for prescription drugs and lowers the costs of prescription drug coverage. Individuals who qualify for the full LIS receive assistance to pay their full premiums and deductibles (in certain Part D plans) and have reduced cost sharing. Individuals who qualify for the partial LIS pay reduced premiums (on a sliding scale based on their income) and also have reduced deductibles and cost sharing.

Currently, in order to qualify for the full subsidy, an individual must live in 1 of the 50 States or the District of Columbia and meet the income and resource standards established in at section 1860D–14(a)(3)(D) of the Act and codified at § 423.773. To be eligible for the full subsidy, individuals must have countable income below 135 percent of the Federal poverty level (FPL) for the individual's family size. In addition, an individual must have resources that do not exceed three times the resource limit under section 1613 for applicants for Supplemental Security Income (SSI) under title XVI. The resource limit increases annually by

the percentage increase in the Consumer Price Index (CPI, all items, U.S. city average) as of September for the year before and is rounded to the nearest multiple of $10. The resource limits in 2006 (at the start of the Part D benefit) were $6,000 for a beneficiary who was single or $9,000 if the beneficiary was married, and in 2022 the amounts are $8,400, if single, or $12,600, if married.

Individuals who are not eligible for the full LIS subsidy may be eligible for the partial LIS subsidy if they live in 1 of the 50 States or the District of Columbia and have incomes below 150 percent of the FPL for their family size and have resources that do not exceed the amounts specified in section 1860D–14(a)(3)(E)(I) of the Act. Similar to the resource limits for the full subsidy group, these amounts are increased annually by the percentage increase in the CPI as of September for the year before and rounded to the nearest multiple of $10. The resource limits for the partial subsidy in 2006 were $10,000 for a beneficiary who was single or $20,000 if the beneficiary was married, and the limits in 2022 are $14,010, if single, or $27,950, if married.

Section 11404 of the Inflation Reduction Act (IRA) (Pub. L. 117–169), enacted on August 16, 2022, amended section 1860D–14 of the Act to expand eligibility for the full LIS subsidy group to individuals with incomes below 150 percent of the FPL and who meet either the resource standard in paragraph (3)(D) or paragraph (3)(E) of section 1860D–14(a) of the Act, beginning on or after January 1, 2024. This change will provide the full LIS subsidy for those who currently qualify for the partial subsidy.

To implement the changes to the LIS income requirements, we propose to amend § 423.773(b)(1) to add that to be eligible for the full subsidy for plan years beginning on or after January 1, 2024, an individual must have an income below 150 percent of the FPL. To coordinate with this change, we are also proposing to amend § 423.773(d) to specify that the requirement that an individual have an income below 150 percent of the FPL to be eligible for the partial subsidy applies only to plan years beginning before January 1, 2024. This latter change will effectively sunset the partial subsidy income requirements after 2023.

To implement the changes to the resource limits, we propose to amend § 423.773 to state that the current resource limits applicable for the full subsidy at paragraph (b)(2)(ii) apply to years 2007 through 2023. We also propose to add a new § 423.773(b)(2)(iii) to state that for years beginning on or after January 1, 2024, the resource limits at paragraph (d)(2) of § 423.773—the resource standards currently applicable for the partial subsidy—would apply to full subsidy eligible individuals.

Lastly, we propose to amend § 423.780(d) to specify that the sliding scale premium amounts currently applicable for individuals with the partial subsidy apply with respect to plan years beginning before January 1, 2024. These individuals who have incomes between 135 and 150 percent of the FPL and who meet the resource requirements will now qualify for the full subsidy beginning in 2024, and will be entitled to a premium subsidy of 100 percent of the premium subsidy amount, as outlined in § 423.780(a).

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152)

1. Introduction

On January 20, 2021, President Biden issued Executive Order (E.O.) 13985: ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' (hereinafter referred to as E.O. 13985).[6] E.O. 13985 describes the Administration's policy goals to advance equity across Federal programs and directs Federal agencies to pursue a comprehensive approach to advancing equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. In response, CMS announced its 2022 CMS Strategic Plan, and ''Advance Equity'' is the first pillar of that Strategic Plan.[7] This pillar emphasizes the importance of advancing health equity by addressing the health disparities that impact our health system. CMS defines health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [8] This is the definition of health equity that we use for all health equity provisions in this proposed rule.

CMS continues to work diligently to identify regulatory actions that can help support CMS's goal to advance health equity or that already address health equity topics but should be expanded in order to meet the increasingly diverse needs of enrollees served by MA organizations. In order to support the Administration's goal of advancing equity for all, it is imperative that we ensure our regulations address topics that enable disadvantaged populations to fully access the care that the regulations already allow them to receive. Consequently, we are proposing several regulatory updates in the MA program related to health equity. These proposals include requirements intended to ensure equitable access to MA services, ensure MA provider directories reflect providers' cultural and linguistic capabilities and notate MOUD-waivered providers, ensure MA enrollees with low digital health literacy are identified and offered digital health education to assist them in accessing any medically necessary covered telehealth benefits, and ensure MA organizations incorporate one or more activities into their overall quality improvement program that reduce disparities in health and health care among their enrollees. CMS believes that the proposed changes included in this proposed rule would address health disparities in the MA program and could be essential to more broadly supporting other equity-focused efforts across CMS policies and programs.

2. Ensuring Equitable Access to Medicare Advantage (MA) Services (§ 422.112)

As discussed extensively in section III.A.1. of this proposed rule, E.O. 13985 describes the Administration's policy goals to advance equity across the Federal Government. Currently, § 422.112(a)(8) requires MA organizations that offer coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

As discussed in the interim final rule with comment period titled, ''Medicare Program; Establishment of the Medicare+Choice Program,'' which appeared in the **Federal Register** on June 26, 1998 (63 FR 34968, 34989) (the June 1998 IFC), the goal of this regulatory requirement was to ensure that enrollees with limited English proficiency, limited education, or other socioeconomic disadvantages receive the health care to which they are entitled. This requirement was part of

[6] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[7] *https://www.cms.gov/cms-strategic-plan.*

[8] *https://www.cms.gov/pillar/health-equity.*

several provisions implementing and setting standards for ensuring access to covered services. CMS later finalized the provision in the final rule titled Medicare Program; Medicare+Choice Program, which appeared in the **Federal Register** on June 29, 2000 (65 FR 40170) (the June 2000 final rule) with a somewhat detailed discussion of the objectives served by this provision (65 FR 40217 through 40218). The principle objective underlying the current requirement to provide services in a culturally competent manner is to address unique racial and ethnically-related health care concerns. However, the regulation explicitly applies to all enrollees and does not include an exception for any enrollees; therefore, this consideration must be part of an MA organization's work in ensuring that all covered benefits are available and accessible to all enrollees. The regulation applies to ''all enrollees'' even though specific populations are mentioned as examples of enrollees to whom services must be provided in a culturally competent manner.

In the June 2000 final rule (65 FR 40217), CMS discussed that appropriate care delivery should accommodate the unique health-related beliefs, attitudes, practices, and communication patterns of beneficiaries and their caregivers to improve services, strengthen programs, increase community participation and eliminate disparities in health status among diverse population groups; CMS also emphasized the importance for health care providers and administrative staff to possess a set of attitudes, skills, behaviors, and policies that enables the organization to effectively provide services to diverse population groups. While § 422.112(a)(8) already applies to all enrollees, CMS believes that amendments to the current regulatory text would better reflect the broad scope of underserved populations that MA organizations must ensure have access to services provided in a culturally competent manner. As the populations that CMS serves become increasingly diverse, it is imperative to keep regulations updated to ensure broad protections are available that minimize the potential for discriminatory barriers, including any electronic tools that use discriminatory algorithms, to surface. Thus, CMS is proposing the following changes and additions to the regulatory language at § 422.112(a)(8) with an intention to clarify the scope of the existing requirements, consistent with the direction and goals of E.O. 13985. CMS notes that the requirements at § 422.112(a)(8) were originally codified using our authority in section 1852(d) of the Act (concerning access to services) as well as our authority in section 1856(b)(1) of the Act to establish standards under Part C; the intent of this proposal is to update the regulatory language at § 422.112(a)(8) for clarification purposes rather than to make actual changes in requirements. We continue to rely on sections 1852(d) and 1856(b)(1) of the Act as the basis for § 422.112, including these changes, consistent with the June 1998 IFC and finalization in a February 1999 final rule (64 FR 7981) of these existing requirements.

The current paragraph heading at § 422.112(a)(8), which precedes the existing equitable access provisions, is titled ''Cultural considerations.'' CMS acknowledges that the term ''cultural considerations'' could create the misconception that the protections of the provisions apply only to some populations and not others. CMS is proposing to revise this heading to ''*Ensuring Equitable Access to Medicare Advantage (MA) Services*.'' The term ''equitable access'' is a broader and more suitable description for the paragraph, as it does not suggest an emphasis on protecting access to care for one population over another. We believe these changes will more clearly reflect the inclusive nature of the protections MA organizations must guarantee for all enrollees under these provisions.

Additionally, the current regulatory language describes some underserved groups as examples of populations that may require accommodations that are specific to their needs—those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds. Amending the text to identify additional types of underserved groups will provide clarity with regard to the populations MA organizations must accommodate in order to meet requirements for access to services. At § 422.112(a)(8), CMS proposes to replace the phrase ''those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds'' after the word ''including'' and to add in its place additional paragraphs listing more examples of underserved populations to whom an MA organization must ensure that services are provided in a culturally competent manner and promote equitable access to services in order to satisfy the existing requirement. The proposed new list would be as follows: (i) people with limited English proficiency or reading skills; (ii) people of ethnic, cultural, racial, or religious minorities; (iii) people with disabilities; (iv) people who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (v) people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (vi) people who live in rural areas and other areas with high levels of deprivation; and (vii) people otherwise adversely affected by persistent poverty or inequality. CMS notes that MA organizations must provide all enrollees, without exception, accommodations to equitably access services according to applicable statutory, regulatory, and other guidance. These provisions should not be construed to mean that accommodations are required only for enrollees who belong to the groups listed herein.

CMS believes these clarifications are necessary and are consistent with the Administration's goal of ensuring equity across Federal programs, consistent with E.O. 13985. CMS welcomes public comment in response to this proposal.

3. Medicare Advantage (MA) Provider Directories (§ 422.111)

Section 1852(c)(1) of the Act requires an MA organization to disclose, among other things, the number, mix, and distribution of plan providers in a clear, accurate, and standardized form to each enrollee in an MA plan offered by the MA organization at the time of enrollment and at least annually thereafter. We implemented this requirement in a regulation at § 422.111(a) and (b)(3)(i), requiring that an MA organization must disclose the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services, in the manner specified by CMS, to each enrollee electing an MA plan it offers; in a clear, accurate, and standardized form; and at the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period. In addition, under § 417.427, the MA disclosure requirements at § 422.111 also apply to section 1876 cost plans.

CMS has historically interpreted the disclosure requirement at § 422.111(b)(3)(i)—''the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services''—as referring to the provider directory. CMS developed the MA and Section 1876 Cost Plan Provider Directory Model,[9] a model material created as an example of how to convey the required information

[9] The current MA and Section 1876 Cost Plan Provider Directory Model is located at: *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.*

to enrollees. In accordance with § 422.2267(c), when drafting their provider directories based on CMS's model, organizations must accurately convey the required information and follow the order of content specified by CMS.

The current provider directory model contains an array of specific required information based on § 422.111(b)(3)(i); we refer to this information collectively as required provider directory data elements. For example, organizations must list only the office or practice location(s) where the provider regularly practices, must clearly identify the capacity in which the provider is serving (that is, specialty type), and must clearly identify whether or not a provider is accepting new patients or provide a notice directing beneficiaries to contact a provider to determine if he or she is accepting new patients. Other examples of required provider directory data elements include up-to-date provider practice names and notations next to providers' listings indicating any restrictions on access. Several of these data elements are tied to how § 422.111(b)(3)(i) requires the organization to disclose information about providers from whom enrollees may reasonably be expected to obtain services; issues of access, including whether the provider is accepting new patients, are integral to whether an enrollee may reasonably be expected to obtain covered services from that provider. In addition, some of these provider directory data elements (for example, restrictions on access notations, accepting new patients indicator) contain important information that organizations should be taking into account to verify that their networks are truly adequate. This enables the organization to ensure that all covered services are available and accessible under the plan, as required by section 1852 of the Act and § 422.112(a).

In addition to the required provider directory data elements, CMS guidance addresses best practices for provider directories, including encouraging organizations to identify non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities. CMS proposes to codify these two best practices (the latter in terms of deaf or hard of hearing individuals) as a regulatory requirement at § 422.111(b)(3)(i). Specifically, we propose to mirror the Medicaid provider directory requirements at § 438.10(h)(1)(vii) by adding the phrase ''each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office'' to paragraph (b)(3)(i). This would change these two best practices to required data elements that all organizations must include in their provider directories. Currently, the Medicaid managed care regulation at § 438.10(h)(1)(vii) requires that provider directories for Medicaid managed care plans include information on the provider's cultural and linguistic capabilities, including languages (including American Sign Language (ASL)) offered by the provider or a skilled medical interpreter at the provider's office as well as other information identifying the provider's location, contact information, specialty, and other information important for beneficiaries in selecting a healthcare provider. The proposal here makes use of the precedent established by the Medicaid program and helps move the agency closer to its goal of aligning the various CMS program requirements.

We note that the phrase ''cultural and linguistic capabilities'' as proposed here for § 422.111(b)(3)(i) refers to the capabilities of a provider (or skilled medical interpreter at the provider's office) to deliver culturally and linguistically appropriate services (CLAS), which are defined by the HHS Office of Minority Health as ''services that are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs.'' [10] As indicated by several research studies, language concordance between providers and limited English proficient individuals is associated with better health outcomes, and so better matching patients with providers who speak the same language is expected to improve quality of care and reduce disparities.[11] CMS believes this important proposed regulatory change would enhance the quality and usability of provider directories, particularly for non-English speaking enrollees searching for providers who speak their preferred language, for limited English proficient individuals, and for those enrollees seeking providers who use ASL themselves or have an ASL interpreter available in their office.

This proposal does not implement, take the place of, or supersede an organization's or provider's obligations to take reasonable steps to ensure meaningful access to such programs or activities by limited English proficient individuals and appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in such programs or activities, including the provision of oral language assistance services and/or auxiliary aids and services when required by applicable law (section 1557 of the Patient Protection and Affordable Care Act (PPACA) and 45 CFR part 92). We are proposing this new requirement for MA provider directories as a standard for implementing and ensuring compliance with section 1852(c)(1)(C) of the Act and as a necessary and appropriate standard to ensure that MA enrollees have the information they need in order to access covered services from an MA plan.

This proposal is also consistent with the health equity objectives of CMS's first strategic pillar ''Advance Equity'' under the 2022 CMS Strategic Plan.[12] It supports current CMS efforts to advance health equity by giving enrollees a fair and just opportunity to access health care services regardless of preferred language. Please refer to sections III.A.1. and III.A.2. of this proposed rule for more extensive discussion of health equity issues in the MA program.

To further enhance our requirements for MA provider directories in the area of behavioral health, we also propose to add a new required provider directory data element for certain providers who offer medications for opioid use disorder (MOUD). Access to MOUD can be life-saving, but too often, patients do not know how to access this type of care. MA enrollees may have little insight as to which providers can provide MOUD. This problem is especially urgent, as overdose deaths from opioids have skyrocketed during the COVID–19 pandemic.[13] Therefore, we propose to require organizations to identify certain providers in their provider directories who have obtained a waiver under section 303(g)(2) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)(2)(B)(i)–(ii)) from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) to treat patients with MOUD (for example, methadone, buprenorphine, naltrexone, naloxone, or Suboxone) and who are listed on SAMHSA's

[10] *https://www.minorityhealth.hhs.gov/Assets/PDF/TCH%20Resource%20Library_CLAS%20CLC%20CH.pdf.*

[11] *https://pubmed.ncbi.nlm.nih.gov/20878497/; https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2599011; https://link.springer.com/article/10.1007/s11606-019-04847-5.*

[12] *https://www.cms.gov/cms-strategic-plan.*

[13] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

Buprenorphine Practitioner Locator (BPL).[14]

Specifically, we propose to include this new regulatory requirement at § 422.111(b)(3)(i) by adding the phrase ''notations for MOUD-Waivered Providers as defined in § 422.116(b)(1)(xxx) who are listed on the Substance Abuse and Mental Health Services Administration's Buprenorphine Practitioner Locator'' to paragraph (i). We are using the term ''MOUD-Waivered Providers'' as section III.B.2. of this proposed rule is proposing to define this term at proposed § 422.116(b)(1)(xxx) as ''providers who are waived by the Substance Abuse and Mental Health Services Administration and the Drug Enforcement Agency to administer, dispense, or prescribe narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment for opioid use disorder in accordance with section 303(g)(2) of the Controlled Substances Act.'' Thus, to avoid duplication and ensure consistency in application of the term, at proposed § 422.111(b)(3)(i), we cross-reference the definition at proposed § 422.116(b)(1)(xxx). This proposed change to the content requirements for provider directories would allow MA enrollees to use their provider directories to search for the providers that have special training to provide MOUD and are allowed to administer, dispense, or prescribe the medications in an office setting.

In order for the organization to flag the provider in its provider directory, the provider must: (1) possess a waiver currently approved by SAMHSA and the DEA; (2) have a valid and active ''X-number'' from the DEA in order to administer, dispense, or prescribe MOUD; and (3) be listed on SAMHSA's BPL (have allowed their practice location to be disclosed publicly).[15] For more information on how providers can become MOUD-waivered providers, see the SAMHSA website.[16] This proposal would require organizations to identify such providers in their provider directories by including notations next to the providers' listings indicating that the providers are able to treat patients with MOUD. No reference to the actual waiver in the provider directory is necessary to provide the necessary notices to the enrollee; however, the organization would need to determine which providers in their network currently have the waiver, have the valid and active ''X-number,'' and are listed in SAMHSA's BPL in order to know which providers to flag in the provider directory as able to treat patients with MOUD. The provider directory would need to include language to indicate the meaning of the MOUD-waivered providers notation, which is that these providers have completed the training so that they may administer, dispense, or prescribe MOUD in an office setting and have agreed to be publicly identified, but that such notations are not inclusive of all providers who may do so.

We believe that this new proposed MA provider directory data element is important and necessary for ensuring access to behavioral health services for MA enrollees. It supports both national and CMS efforts related to behavioral health priorities and strategies, as described in section III.B.1. of this proposed rule. This proposal will help MA enrollees struggling with OUD find providers who can treat them by prescribing MOUD, moving them further along the path towards long-term recovery.

If finalized, CMS intends to monitor organization compliance with the proposed new requirements described here through periodic online provider directory reviews, as CMS deems necessary, and other activities that are consistent with CMS's existing compliance monitoring regarding provider directory requirements.

These proposals to amend § 422.111(b)(3)(i) both codify as new requirements certain existing guidance on best practices and introduce a new provider directory data element. Organizations that do not currently collect data on their contracted providers' cultural and linguistic capabilities or their status as a MOUD-waivered provider may do so by using the same means and methods by which they already collect other information from contracted providers for inclusion in provider directories. Also, organizations would use SAMHSA's BPL to identify approved providers who have allowed their practice location to be disclosed. We expect this proposed provision to impose an additional minimal amount of information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) on organizations in terms of the updating of their existing processes related to provider directories, such as a template, related software, and the added data points for providers. However, we believe this burden does not need to be submitted to the Office of Management and Budget (OMB) based on the currently approved control number 0938–0753 (CMS–R–267), which states: ''The additional burden of translating this network into a directory which is posted on the plan website as well as the update and maintenance of this directory is part of the usual and customary normal business activities and as such is exempt from PRA by 5 CFR 1320.3(b)(2).'' Consequently, there is no need for review by OMB under the authority of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

In summary, CMS is proposing to add two new requirements to § 422.111(b)(3)(i) that organizations must include providers' cultural and linguistic capabilities and identify certain providers waived to treat patients with MOUD in their provider directories. We solicit comment on these proposed improvements to the content of MA provider directories. We also refer readers to section III.B.2. of this proposed rule for our proposal to add prescribers of MOUD as a new specialty type to be subject to MA network adequacy evaluation.

4. Digital Health Education for Medicare Advantage (MA) Enrollees Using Telehealth (§ 422.112)

Telehealth has become increasingly popular and essential to providing access to health care, especially during the COVID–19 Public Health Emergency (PHE). For the purposes of this section of this proposed rule, we are using the term ''telehealth benefits'' very broadly to encompass covered services that are furnished to the enrollee (that is, the patient) in a different location than where the provider is located; there are multiple categories of covered benefits where this circumstance is present, with additional criteria or requirements applying to different categories of covered benefits when the enrollee and provider are not in the same place at the time the service is furnished. Under the MA program, there are various requirements and options for coverage of telehealth benefits. When original Medicare covers telehealth benefits, such as services described in section 1834(m) of the Act and § 411.78, MA organizations must cover those telehealth benefits as basic benefits, as defined in § 422.100(c). If an MA organization wishes to offer telehealth benefits that go beyond the scope of the original Medicare telehealth benefits

[14] *https://www.samhsa.gov/medication-assisted-treatment/find-treatment/treatment-practitioner-locator.*

[15] *https://www.samhsa.gov/medication-assisted-treatment/find-treatment/treatment-practitioner-locator.*

[16] *https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner.*

that must be covered by every MA plan, MA organizations have the option to offer ''Additional Telehealth Benefits'' (ATBs) and/or supplemental telehealth benefits. Section 1852(m) of the Act and § 422.135 outline the requirements for ATBs, which are generally services for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act, and the services are furnished when the patient and the physician or practitioner are not in the same location. If an MA organization wishes to offer telehealth benefits that are not covered by original Medicare and are not within the scope of § 422.135, then the MA organization may choose to offer them as supplemental benefits. The requirements for MA supplemental benefits are set forth at section 1852(a)(3) of the Act and §§ 422.100(c) and 422.102. An MA organization's bid must accurately reflect the covered telehealth service, whether it is covered as an ATB or a supplemental benefit. In addition, during the COVID–19 PHE, MA organizations have been required to take into account the various waivers, amendments to regulations, and other guidance published by CMS, with regard to telehealth benefits. In using the term ''telehealth benefits'' here, we mean to include all of these various categories of covered benefits. In the regulation text we are proposing here, we use the phrase ''covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135'' as a means to encompass all of the potential covered benefits included in our broad use of the term ''telehealth benefits.'' As defined in § 422.135, electronic exchange means electronic information and telecommunications technology, which we believe is broad enough to include telecommunications and technologies permitted for covered Part B services under section 1834(m) of the Act and implementing regulations as well as MA ATBs and other supplemental benefits.

In recent years, CMS has seen a significant boost in the offering of telehealth benefits in the MA program. Almost 99 percent of MA plans offered some form of telehealth benefits in contract year 2022, either in the form of ATBs or supplemental telehealth benefits. This is a 16 percent increase since contract year 2018 and a 9 percent increase since contract year 2020, which was the first year MA organizations were permitted to offer ATBs. ATB offerings alone have increased by approximately 39 percent since their inception 2 years ago. The total number of MA enrollees who have access to MA telehealth benefits of any kind has risen from approximately 89 percent in contract year 2018 to nearly 100 percent in contract year 2022.

While the supply and demand of telehealth has clearly grown in recent years, there is evidence that barriers to accessing telehealth leave room to improve health equity in telehealth. The regulatory change we are proposing here is an attempt to improve health equity in telehealth and is consistent with both E.O. 13985 and CMS's first strategic pillar ''Advance Equity'' under the 2022 CMS Strategic Plan.[17] [18] For purposes of this provision, we are using CMS's definition of health equity, which is included in section III.A.1. of this proposed rule.[19] In developing this proposal, we are also guided by HHS's definition of ''health equity in telehealth'' as meaning the ''opportunity for everyone to receive the health care they need and deserve, regardless of social or economic status. Providing health equity in telehealth means making changes in digital literacy, technology, and analytics, which will help telehealth providers reach the underserved communities that need it the most.'' [20]

Health equity in telehealth is difficult to attain due to barriers to telehealth access, which may include: lack of video sharing technology (for example, a smartphone, tablet, or computer), spotty or no internet access, lack of housing or private space to participate in virtual visits, few local providers who offer telehealth practices, language barriers (including oral, written, and signed language), the inability to incorporate third party auxiliary aids and services such as live captioners, telehealth software, apps, and websites that are accessible and usable by people with disabilities, and lack of adaptive equipment for people with disabilities along with incompatibility with external assistive technologies used by people with disabilities.[21] These barriers are especially burdensome on populations that may already experience health disparities, such as those who are adversely affected by persistent poverty and inequality, those who live in rural areas, people from some racial and ethnic groups, immigrants, people who identify as LGBTQI+, people with disabilities, older people, limited English proficient individuals, people with limited digital literacy, and people who are underinsured or uninsured. Such underserved communities often lack equitable access to health care, leading to consequences such as: higher mortality and disease rates, more severe disease and illness, higher medical costs, lack of access to treatment, and lack of access to health insurance.[22]

The existence of communities with low digital health literacy who in turn cannot access telehealth represents a significant obstacle in achieving health equity in telehealth. The World Health Organization defines digital health literacy as ''the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem. Examples of digital health literacy include accessing your electronic health record, communicating electronically with your health care team, ability to discern reliable online health information, and using health and wellness apps.'' [23] Low digital health literacy can impact an individual's access to or quality of telehealth visits.[24] Evidence shows that those with low digital health literacy tend to be older, lower income, less educated, and Black or Hispanic.[25]

Many older adults with low digital health literacy experience gaps in access to the health care they need, and this is concerning for the MA program, whose enrollee population includes individuals age 65 and older (as well as individuals under age 65 with disabilities). For example, the American Association of Retired Persons (AARP) annual technology survey found that more than half of older adults (age 50 and older) in 2021 indicated they need more digital education, while more than one in three said they lacked confidence when using technology.[26] Of the 32

[17] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[18] *https://www.cms.gov/cms-strategic-plan.*

[19] *https://www.cms.gov/pillar/health-equity.*

[20] *https://telehealth.hhs.gov/providers/health-equity-in-telehealth/.*

[21] Valdez R.S., Rogers C.C., Claypool H., Trieshmann L., Frye O., Wellbeloved-Stone C., Kushalnagar P. Ensuring full participation of people with disabilities in an era of telehealth. J Am Med Inform Assoc. 2021 Feb 15;28(2):389–392. doi: 10.1093/jamia/ocaa297. PMID: 33325524; PMCID: PMC7717308.

Annaswamy TM, Verduzco-Gutierrez M, Frieden L. Telemedicine barriers and challenges for persons with disabilities: COVID–19 and beyond. Disabil Health J. 2020;13(4):100973. doi:10.1016/j.dhjo.2020.100973.

[22] *https://telehealth.hhs.gov/providers/health-equity-in-telehealth/.*

[23] *https://nnlm.gov/guides/intro-health-literacy.*

[24] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8464820/.*

[25] *https://nces.ed.gov/pubs2018/2018161.pdf.*

[26] Kakulla, Brittne. 2021 Tech Trends and the 50-Plus: Top 10 Biggest Trends. Washington, DC:

Continued

million Americans who cannot use a computer, approximately one-third are seniors.[27] Further, less than one-third of Medicare beneficiaries over 65 have at-home digital access, and those over age 75 and with less than high school-level education are less likely to use telehealth.[28] For people with disabilities, 15 percent reported not using the internet as opposed to 5 percent in the general population in a Pew Foundation Survey, while 62 percent of people with disabilities as opposed to 81 percent of the general population own their own desktop or laptop computer.[29] Other studies have confirmed a significant gap in digital literacy among people with disabilities.[30] Another survey found that Black, Latino, and Filipino seniors and those 75 years and older are significantly less likely to own devices like computers and smartphones compared to non-Hispanic whites, Chinese, and younger seniors (ages 65–69); this was also true in terms of these groups' respective use of the internet and email, as well as their ability and willingness to use technology for telehealth purposes.[31]

As outlined here, research indicates that older adults, people with disabilities, people from some racial and ethnic groups, rural communities, underserved populations, and those adversely affected by persistent poverty and inequality are all disadvantaged by limited access to modern information and communications technology (sometimes referred to as a digital divide).[32] Individuals with a higher degree of digital health literacy receive more healthcare information, are better equipped to evaluate the quality of information regarding their healthcare, and report higher telehealth usage.[33] Further, individuals with chronic diseases also benefit from digital health literacy; when such individuals possess digital health literacy, they tend to monitor and manage their diseases more competently, are more satisfied with the telemedicine services, and respond faster to changes that might adversely affect their situation, thereby improving their overall health.[34] This is significant because individuals with two or more chronic diseases are more likely to be individuals 65 and over.[35]

CMS does not currently have requirements for MA organizations in the area of digital health literacy. Given the need to increase digital health literacy in many communities with MA enrollees and the goal to achieve health equity in telehealth, we believe it is necessary to implement regulations addressing digital health literacy in the MA program. CMS expects that these digital health literacy proposals, if finalized, would help underserved communities in need of assistance to improve their digital health literacy and help advance the goal of achieving health equity in telehealth.[36]

We propose to add requirements for MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist them with accessing any medically necessary covered telehealth benefits. Specifically, we propose to amend current continuity of care requirements for MA organizations offering coordinated care plans to ''ensure continuity of care and integration of services through arrangements with contracted providers'' at § 422.112(b), by adding a new paragraph (9). The new proposed paragraph would require MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange; we use the term ''electronic exchange'' as it is broadly defined in § 422.135. This proposed new continuity of care requirement would apply to all MA organizations offering coordinated care plans (that is, HMOs, PPOs, HMO–POSs, and SNPs) and would be relevant for all types of covered telehealth benefits, including basic telehealth benefits, ATBs, and supplemental telehealth benefits offered by MA coordinated care plans. We solicit comment on whether to amend § 422.100 instead of § 422.112(b) in order to apply this new requirement to all MA plans and not just coordinated care plans. This proposed additional standard is intended to ensure that MA enrollees are able to access covered benefits and that MA organizations meet their obligations under section 1852(d) of the Act to make covered benefits available and accessible to enrollees in the plan. Section 1856(b) of the Act authorizes the adoption of standards that are consistent with and to carry out the Part C statute. As telehealth benefits become more prevalent in the MA program, taking steps to provide enrollees with digital health education will ensure that these telehealth benefits are truly accessible and available to enrollees.

This proposal would be a first step for MA organizations to assess the landscape of health equity in telehealth in their plans and help enrollees navigate telehealth. Under this proposal, CMS would provide a degree of discretion for MA organizations in the procedures developed and used to identify enrollees with low digital health literacy and the digital health education services the MA organization provides for those enrollees. In order to comply with the proposed new regulation, MA organizations would necessarily have to introduce a digital health literacy screening program or other similar procedure to identify current enrollees with low digital health literacy, however, MA organizations would have flexibility to design their own screening program or procedure. Some experts recommend such an assessment should examine patient-level barriers such as telehealth readiness, broadband access, and inaccessible or unusable information and communication technologies by individuals with disabilities that limit patient use of telehealth.[37] Others recommend considering certain digital foundation skills based on a specific framework.[38] CMS encourages MA organizations to research current trends and successes in the field when developing their own methods to identify enrollees with low digital

AARP Research, April 2021. *https://doi.org/10.26419/res.00420.001.*

[27] *https://www.telehealthequitycoalition.org/improving-digital-literacy-to-improve-telehealth-equity.html.*

[28] Shah M.K., Gibbs A.C., Ali M.K., Narayan K.M.V., Islam N. Overcoming the Digital Divide in the Post–COVID–19 ''Reset'': Enhancing Group Virtual Visits with Community Health Workers J Med internet Res 2021;23(7):e27682 doi: 10.2196/27682.

[29] Andrew Perrin and Sara Atske, *Americans with disabilities less likely than those without to own some digital devices, Pew Research, September 10, 2021,* online at *https://www.pewresearch.org/fact-tank/2021/09/10/americans-with-disabilities-less-likely-than-those-without-to-own-some-digital-devices/.*

[30] Eun Ji Kim, MS, MD, Yiyang Yuan, MS, MPH, Jane Liebschutz, MPH, MD, Howard Cabral, MPH, Ph.D.,[4] and Lewis Kazis, ScD, Understanding the Digital Gap Among US Adults With Disability: Cross-Sectional Analysis of the Health Information National Trends Survey 2013, *JMIR Rehabil Assist Technol.* 2018 Jan–Jun; 5(1): e3. Online at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4799429/.*

[31] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4799429/.*

[32] *https://academic.oup.com/jamia/article/27/12/1949/5899728.*

[33] *https://jamanetwork.com/journals/jama/article-abstract/2426088.*

[34] *https://www.sciencedirect.com/science/article/pii/S0738399114001876.*

[35] *https://www.cdc.gov/pcd/issues/2020/20_0130.htm.*

[36] *https://telehealth.hhs.gov/providers/health-equity-in-telehealth/.*

[37] *https://link.springer.com/content/pdf/10.1007/s00520-021-06629-4.pdf.*

[38] *https://www.digitalinclusion.org/definitions/.*

health literacy. CMS anticipates that some MA organizations could ask enrollees, for example, if they have internet access and reliable connectivity, if they have a device that meets appropriate telehealth system requirements, if they use email, if they can download a mobile app, or if they can change applicable settings on a device (for example, browser or camera settings), as a means to identify which enrollees have low digital heath literacy.[39]

Once the MA organization determines which enrollees experience low digital health literacy, the MA organization would then have to implement a digital health education program to offer to these enrollees. CMS is not proposing to identify explicit parameters for this digital health education requirement, rather, we have chosen to keep it flexible and allow for innovation in this area by MA organizations. Depending on the specific enrollment in an MA plan, the procedures to identify enrollees and the mechanisms and content of the digital health education could vary. However, some examples of digital health education designs include: distributing educational materials about how to access certain telehealth technologies in multiple languages, including sign language, and in alternative formats; holding digital health literacy workshops; integrating digital health coaching; offering enrollees in-person digital health navigators; and partnering with local libraries and/or community centers that offer digital health education services and supports.

As a best practice, CMS encourages MA organizations to ensure that there are no system requirements (for example, online portal enrollment) that could act as barriers to accessing covered telehealth benefits, or the proposed digital health education for enrollees with low digital health literacy, so as to promote ease of access in the simplest way possible. In addition, if an MA organization offers enrollees assistance with any necessary telehealth technology—for instance, if they provide limited use smartphones/tablets or cellular data plans as supplemental benefits in order to aid in the use of telehealth services—then the MA organization must comply with applicable laws about those benefits and make enrollees aware of these available benefits per section 1852(c)(1)(F) of the Act and § 422.111(b)(6). This disclosure is especially important for enrollees identified as having low digital health literacy. Smartphones and tablets (or other similar equipment) must only be used for primarily health related purposes (and cellular data plans can only be provided if use of these plans is locked and limited to health-related activities), such as when the device is locked except for remote monitoring or to enable engagement with health care providers, in order for these items and services to be permissible supplemental benefits under § 422.100(c)(2)(ii). However, furnishing or covering a cellular data plan without limitations might be permissible (under section 1852(a)(3)(D) of the Act and § 422.102(f)) as a non-primarily health related special supplemental benefit for the chronically ill (SSBCI) when the benefit is limited to a chronically ill enrollee and has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. For more information on SSBCI, please see the June 2020 final rule and the Medicare and Medicaid Programs; Contract Year 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 final rule which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) (hereinafter referred to as the January 2021 final rule). CMS encourages MA organizations whose plans have a high number of enrollees with low digital health literacy to consider offering the aforementioned supplemental benefits and pairing an appropriate digital health education program with the provision of such devices to enrollees, where permitted by applicable law.

To further emphasize the importance of health equity and health equity in telehealth specifically, CMS reminds MA organizations that § 422.112(a)(8) as it currently reads requires MA organizations offering coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees, including limited English proficient individuals or those with limited reading skills, and those with diverse cultural and ethnic backgrounds. CMS is proposing, in section III.A.2. of this proposed rule, to amend § 422.112(a)(8) to better reflect the broad scope of potentially underserved populations and to emphasize how MA plans must ensure equitable access to services. As adopted and with our proposed revisions, § 422.112(a)(8) requires MA organizations to ensure that services are provided in an equitable manner to all enrollees. MA organizations must take into account these additional obligations, as applicable, when developing and maintaining the digital health education programs they would be required to implement under this proposal. Furthermore, the HHS Office for Civil Rights and the U.S. Department of Justice (DOJ) Civil Rights Division recently published new guidance providing clarity on how Federal nondiscrimination laws require accessibility for people with disabilities and limited English proficient individuals in health care provided via telehealth.[40] These Federal civil rights laws—including the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, title VI of the Civil Rights Act of 1964, and section 1557 of the PPACA—require that telehealth be accessible to people with disabilities and limited English proficient individuals. CMS strongly encourages MA organizations and their contracted providers to review this new guidance issued by HHS and DOJ to ensure compliance with Federal civil rights laws pertaining to telehealth.

In order to monitor the impact of our new proposed requirement for digital health literacy screening and digital health education programs—on MA organizations, providers, enrollees, and the MA program as a whole—we are also proposing to require MA organizations to make information about these programs available to CMS upon request, per proposed § 422.112(b)(9)(i). We propose that this requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of § 422.112(b)(9). The purpose of requiring MA organizations to make such information available to CMS upon request would be to identify best practices for improving digital health literacy amongst MA enrollees and to determine whether CMS should make improvements to the regulation and/or guidance regarding this requirement. We note that the regulation text at proposed § 422.112(b)(9)(i) includes the language ''upon request,'' which we intend here to communicate that CMS

[39] *https://www.telehealthequitycoalition.org/improving-digital-literacy-to-improve-telehealth-equity.html.*

[40] *https://www.hhs.gov/sites/default/files/guidance-on-nondiscrimination-in-telehealth.pdf.*

does not intend to establish uniform data collection from all MA organizations at this time, but instead reserves the right to ask for this information from individual MA organizations. However, we note that our proposed § 422.112(b)(9)(i) would not limit CMS's audit access when program audits review the performance of MA organizations. We solicit comment on this aspect of our proposal and whether we should require regular reporting of data of this type from all MA organizations alongside other Part C reporting requirements.

This proposal to amend § 422.112(b) would impact MA organizations in terms of the burden required to both identify enrollees with low digital health literacy and to develop digital health education programs for these enrollees. However, our estimated analysis of these impacts is qualitative in nature as we are proposing to provide MA organizations flexibility in determining how they wish to implement these proposed CMS requirements. CMS does not currently collect data regarding digital health literacy among MA enrollees and therefore, we have no way of knowing or estimating the extent of low digital health literacy specifically among MA organizations' enrollees, how MA organizations would approach digital health literacy screening and digital health education, how much spending they would engage in related to these efforts, how much savings they would encounter (due to improved enrollee health outcomes because of improved digital health literacy), for example, how much time they would spend on these efforts, or how the MA program would grow as we see the effects of the proposed regulation. We estimate the direct qualitative burden consists of MA organization staff hours spent, resources purchased, and any digital health education for enrollees performed. MA organizations may also differ in how their spending for the proposed requirements evolves over time as they test strategies and redevelop their approaches to complying with the regulation. Thus, the proposed provision would impose an unknown amount of information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) because burden cannot be quantified. We solicit comment from MA organizations on how much burden they expect this proposed provision might add. Regarding the impact of the proposed requirement for the MA organization to make information about its digital health literacy screening and digital health education programs available to CMS upon request, we do not anticipate requesting this information from more than nine MA organizations in a given year. However, we believe it is important to reserve the right to ask for this information if necessary and have structured the proposed regulation text accordingly. Since we estimate fewer than ten respondents, the information collection requirement is exempt (5 CFR 1320.3(c)) from the requirements of the PRA of 1995 (44 U.S.C. 3501 *et seq.*). Consequently, there is no need for review by OMB under the authority of the PRA.

In terms of economic impact on the Medicare Trust Fund, we do expect that improved digital health literacy would increase telehealth visits, which in turn would increase prevention of MA enrollee illness, both of which affect Medicare Trust Fund spending. Yet we have no way of knowing or estimating how much of an increase in telehealth visits there would be, for what specific services they would increase, or the effects of prevented future illnesses among MA enrollees. Thus, this provision is expected to have an unknown economic impact on the Medicare Trust Fund.

In summary, CMS is proposing to add a new requirement at § 422.112(b)(9) that MA organizations must have procedures to identify enrollees with low digital health literacy and offer them digital health education to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135. In addition, the proposal includes a requirement that MA organizations make information about these programs available to CMS upon request. We solicit comment on this proposal.

5. Quality Improvement Program (§ 422.152)

In accordance with section 1852(e) of the Act, all MA organizations must have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to enrollees. Per § 422.152(a), MA organizations must develop a QI plan that sufficiently outlines the QI program elements; have a chronic care improvement program (CCIP) that meets the requirements at § 422.152(c) and addresses populations identified by CMS based on a review of current quality performance; and, encourage its providers to participate in CMS and HHS quality improvement initiatives.

Section 422.152(c) provides that CCIPs must include methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a CCIP; mechanisms for monitoring MA enrollees that are participating in the CCIP and evaluating participant outcomes, such as changes in health status; performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research, and systematic and ongoing follow-up on the effect of the CCIP. Organizations must report the status and results of each program to CMS as requested. The intent of the CCIPs is to promote effective chronic disease management and improve care and health outcomes for enrollees with chronic conditions. Furthermore, CCIPs should support the CMS Quality Strategy; include interventions that surpass MA organizations' inherent care coordination role and overall management of enrollees; engage enrollees as partners in their care; promote utilization of preventive services; facilitate development of targeted goals, specific interventions, and quantifiable, measurable outcomes; guard against potential health disparities; and produce best practices.[41]

In accordance with 1852(e) of the Act, MA organizations are required to report quality performance data to CMS. MA organizations generally report such data through the Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), Consumer Assessment of Healthcare Providers and Systems (CAHPS), and other related data collection tools. As codified at § 422.152(b)(3) and (5), MA coordinated care plans are required to report on quality performance data which CMS can use to help beneficiaries compare plans; MA local and regional PPO plans must similarly report under § 422.152(e)(2)(i). The areas of measurement include outcomes, patient experience, access, and process measures. In addition, CMS uses this information to develop and publicly post a 5-star rating system for MA plans based on its authority to disseminate comparative information, including about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act.

Lastly, to meet the needs of their enrolled special needs populations, MA special needs plans (SNPs) have

[41] *https://www.cms.gov/Medicare/Health-Plans/Medicare-Advantage-Quality-Improvement-Program/5CCIP.*

additional QI program requirements, including the implementation of an approved model of care (MOC), which serves as the framework for meeting the individual needs of SNP enrollees, and the infrastructure to promote care management and care coordination (see § 422.152(g)). As part of the initial MA SNP application and renewal requirements and through MOC submissions, SNPs provide to CMS a detailed profile of the medical, social, cognitive, and environmental aspects, the living conditions, and the co-morbidities associated with the SNP population, including information about health conditions impacting SNP enrollees along with other characteristics that affect health, such as population demographics (for example, average age, sex, gender, ethnicity), and potential health disparities associated with specific groups (for example, language barriers, deficits in health literacy, poor socioeconomic status, cultural beliefs/barriers, caregiver considerations, or other). SNPs must also capture limitations and barriers that pose potential challenges for accessing care and/or maintaining and improving SNP enrollee health status.

Additionally, through health risk assessments (HRAs), SNPs identify the medical, functional, cognitive, psychosocial, and mental health needs of their enrollees, who are all special needs individuals, and address those needs in an individualized care plan for each enrollee. In the final rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' which appeared in the **Federal Register** May 9, 2022 (87 FR 27704), CMS finalized a new requirement for SNPs at § 422.101(f)(1)(i), requiring the HRA tool to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on the domains of housing stability, food security, and access to transportation beginning in 2024. We expect that this data collection would also provide information to MA organizations about potential health disparities among their enrollees.

Persistent inequities in health care outcomes exist in the United States, including among populations enrolled in MA organizations.[42] Belonging to a racial or ethnic minority group, living with a disability, being a member of the LGBTQI+ community, having limited English proficiency, living in a rural area, or being near or below the poverty level, is often associated with worse health outcomes.[43] [44] [45] [46] [47] [48] [49] Such disparities in health outcomes are the result of a number of factors and exist regardless of health insurance coverage type. Although not the sole determinant, poor health care access and provision of lower quality health care contribute to health disparities. Research has shown that the expansion of health insurance coverage, for example through Medicaid expansion under the ACA, and the resulting increased access to health care, is linked to reductions in disparities in health insurance coverage as well as reductions in disparities in health outcomes.[50]

In the final rule titled ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023'', which appeared in the **Federal Register** May 6, 2022 (87 FR 27208), CMS finalized a proposal to update the quality improvement strategy (QIS) standards for qualified health plan (QHP) issuers, requiring them to address health and health care disparities as a specific topic area within their QIS beginning in 2023. Examples of QIS activities that fall under the health and health care disparities topic area for QHPs can include language services, community outreach, cultural competency trainings, social needs-sensitive self-management recommendations, and increased demographic and disparities-related data collection; see the QIS Technical Guidance and User Guide for the 2023 Plan Year for more information. CMS is committed to advancing health equity for MA enrollees. Based on CMS' definition of health equity and in alignment with similar CMS programs, we believe that MA organizations' QI programs are an optimal vehicle to develop and implement strategies and policies designed to reduce disparities in health and health care, and advance equity in the health and health care of MA enrollee populations, especially those that are underserved.

MA organizations have long focused on addressing health disparities through QI program requirements. By assessing cultural, language, health literacy, financial, psychosocial & family support, community networks, and transportation needs, etc., and addressing those needs through a variety of QI program activities across their enrollee populations, MA organizations gain insight into their enrollee populations. Some of the specific QI activities include addressing barriers to health care, for example assisting enrollees with transportation to follow-up primary care visits post-hospitalization, linking enrollees to community resources, and improving care coordination and case management, especially for vulnerable and/or underserved enrollees. In addition to implementing QI activities for the broader enrollee populations, we are aware that some MA organizations have focused their QI activities on underserved groups. For example, to better serve these groups, several MA organizations have made efforts to improve their communication by providing cultural trainings for their staff, tailoring enrollee materials to ensure they are linguistically and culturally appropriate, and hiring plan staff and establishing contracts with providers who are bilingual. Some MA organizations have implemented specific interventions that target blood pressure control, or improved rates for various cancer screenings in targeted groups. These types of activities can

[42] Disparities in Health Care in Medicare Advantage by Race, Ethnicity and Sex, April 2022.

[43] Lindenauer, P.K., Lagu, T., Rothberg, M.B., Avrunin, J., Pekow, P.S., Wang, Y., Krumholz, H., & Hines, H. (2013). Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal.

[44] Trivedi, A.N., Nsa, W., Hausmann, L.R.M., Lee, J., Ma, A., Bratzler, D., Mor, M., Baus, K., Larbi, F., & Fine, M. (2014). Quality and Equity of Care in U.S. Hospitals. *New England Journal of Medicine.* 371(24):2298–2308.

[45] Polyakova, M., Udalova, V., Kocks, G., Genadek, K., Finlay, K., & Finkelstein, A.N. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health affairs (Project Hope), 40 (2), 307–316. *https://doi.org/10.1377/hlthaff.2020.02142.*

[46] Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. (2018). Rural Health Research Gateway. *https://www.ruralhealthresearch.org/recaps/5.*

[47] 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. (2020). HHS Office of Minority Health. *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[48] Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity. (2021, February 5). CDC. *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[49] Poteat, T.C., Reisner, S.L., Miller, M., & Wirtz, A.L. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv: The preprint server for health sciences, 2020.07.21.20159327. *https://doi.org/10.1101/2020.07.21.20159327.*

[50] Guth, M., Garfield, R., & Rudowitz, R. (2020). The Effects of Medicaid Expansion Under the ACA: Studies from January 2014 to January 2020. Kaiser Family Foundation. *https://www.kff.org/medicaid/report/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review/.*

improve the health of and healthcare for MA enrollees.

To improve the quality of care and health outcomes for MA enrollees and support the first pillar in the 2022 CMS strategic plan for advancing health equity, CMS proposes to amend the MA QI program regulations at § 422.152(a). Specifically, we propose to amend § 422.152 by adding a new paragraph (a)(5), to require MA organizations to incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees. As previously described, we believe that many MA organizations are already addressing disparities and gaps in care for underserved populations through a variety of quality initiatives. Rather than limit these activities to specific QI program requirements such as the CCIPs, we are proposing that MA organizations would be required to incorporate one or more activities that reduce disparities in health and health care across the broad spectrum of QI program requirements. CMS expects that MA organizations may implement activities such as improving communication, developing and using linguistically and culturally appropriate materials (to distribute to enrollees or use in communicating with enrollees), hiring bilingual staff, community outreach, or similar activities. MA organizations should tailor these activities to meet the needs of their enrollees, and therefore CMS is generally not proposing to be prescriptive in the types of activities MA organizations must implement to meet this proposed new requirement. However, MA organizations must ensure that these activities are broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparity in health or health care. Furthermore, we believe adopting this proposed requirement for MA organizations as part of their required QI programs will align with health equity efforts across CMS policies and programs. CMS believes that several organizations have already incorporated these activities into their QI programs, thereby meeting the proposed requirement.

B. Behavioral Health in Medicare Advantage (MA) (§§ 422.112, 422.113, and 422.116)

1. Introduction

On March 1, 2022, President Biden announced a national strategy regarding behavioral health to strengthen system capacity and connect more individuals to care by ensuring that the nation's health and social services infrastructure addresses mental health holistically and equitably.[51] Further, the 2022 CMS Strategic Framework describes CMS' broad goals to expand coverage and enhance access to equitable health care services for those covered under CMS programs.[52] CMS is also prioritizing, as part of the agency's many cross-cutting initiatives, to improve access to behavioral health services and outcomes for people with behavioral health care needs.

According to the Health Resources and Services Administration (HRSA), more than one-third of Americans live in designated Mental Health Professional Shortage Areas,[53] meaning these communities do not have enough providers to meet the needs of their population. Furthermore, according to the results from the 2020 National Survey on Drug Use and Health, published by SAMHSA, while overall 65 percent of people with serious mental illnesses (SMI) receive treatment,[54] people of color with SMI receive care at significantly lower rates. More specifically, while approximately 69 percent of white people with SMI received mental health care, for Black, Hispanic, and Asian people with SMI the rates were 55 percent, 56 percent, and 44 percent respectively.[55] The 2020 National Survey results also indicate that common reasons for not receiving treatment for SMI include: inability to afford the cost of treatment, not knowing where to go to receive services, and health insurance not covering services.[56] CMS recently included a request for information (RFI) in the proposed rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' published in the **Federal Register** January 12, 2022 (87 FR 1842) (hereinafter referred to as the January 2022 proposed rule), to solicit public comment regarding the challenges that exist with accessing behavioral health providers within MA plans. We sought stakeholders' input concerning a range of topics, including the challenges related to building behavioral health networks for MA plans, accessing behavioral health providers for MA enrollees, and requesting suggestions on how to address issues with building adequate behavioral health networks within MA plans. We received a number of comments from stakeholders, some of which are discussed later in this preamble in connection with specific proposals.

CMS continues to evaluate and seek ways to enhance our behavioral health policies to address the healthcare needs of those we serve. In order to support these goals, we are proposing regulatory changes that focus on ensuring access to behavioral health services for MA enrollees.

We welcome comment on our proposals.

2. Behavioral Health Specialties in Medicare Advantage (MA) Networks (§§ 422.112 and 422.116)

Section 1852(d)(1) of the Act permits an MA organization to select the providers from which an enrollee may receive covered benefits, provided that the MA organization, in addition to meeting other requirements, makes such benefits available and accessible in the service area with promptness and in a manner which assures continuity in the provision of benefits. To implement and adopt related standards for this, CMS codified, with some modifications, network adequacy criteria and access standards that were previously outlined in sub-regulatory guidance in the ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program'' final rule, which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796), hereinafter referred to as the June 2020 final rule. In that final rule, we codified, at § 422.116(b), the list of 27 provider specialty types and 13 facility specialty types subject to CMS network adequacy standards. Although § 422.116(b)(3) authorizes removal of a specialty or facility type from the network evaluation criteria for a specific year without rulemaking, CMS did not adopt

[51] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/.*

[52] *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

[53] *https://data.hrsa.gov/topics/health-workforce/shortage-areas.*

[54] *https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf.*

[55] *https://www.samhsa.gov/data/sites/default/files/reports/rpt35324/2021NSDUHMHChartbook102221B.pdf.*

[56] *https://www.apa.org/monitor/2020/07/datapoint-care.*

in § 422.116 a mechanism to add new provider types without rulemaking. We are proposing to add to the list of provider specialties here to address access to behavioral health services more broadly than the current regulation.

Currently, MA organizations are required to demonstrate that they meet network adequacy for two behavioral health specialty types, psychiatry and inpatient psychiatric facility services, under § 422.116(b). Further, the regulation at § 422.112 includes a number of requirements to ensure that MA enrollees have adequate access to covered services. Of note, § 422.112(a)(1) requires MA organizations to maintain and monitor a network of appropriate providers that provides access to typically used services including, primary care providers, specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics and other providers.

In response to the RFI in the January 2022 proposed rule, we received comments emphasizing the importance of network adequacy and ensuring adequate access to behavioral health providers in MA plans. Stakeholders suggested that CMS expand the network adequacy time and distance standards for MA plans beyond those that we currently review through our network adequacy evaluations. Commenters suggested that we expand the standards to add other outpatient behavioral health physicians and health professionals, including those that treat substance use disorders (SUDs), that can meet MA enrollees needs in accessing behavioral healthcare.

Even though over one million Medicare beneficiaries had a diagnosis of Opioid Use Disorder (OUD) and more than fifty thousand experienced an overdose in 2021, fewer than 1 in 5 of these Medicare beneficiaries with a diagnosis of OUD receive treatment for their OUD.[57] Current standards of care for OUD include treatment through three Food and Drug Administration (FDA) approved medications (buprenorphine, naltrexone and methadone), along with other services to provide the best approach to treating SUD. Enrollees can access Medications for Opioid Use Disorder (MOUD) in various settings including in Opioid Treatment Programs (OTPs) and through qualified practitioners (physicians, nurse practitioners, physician assistants, etc.) who have obtained a waiver through SAMHSA to dispense these medications in office settings.

CMS is committed to ensuring that MA enrollees have access to provider networks sufficient to provide covered services, including access to behavioral health service providers. Medicare fee-for-service claims data for 2020 shows that for certain outpatient behavioral health services, the top provider specialty types to provide services to beneficiaries included psychiatrists, clinical social workers, nurse practitioners, and clinical psychologists. OTPs had the largest number of claims for SUD in this same time period. Therefore, we propose to strengthen our network adequacy requirements for MA plans as it relates to behavioral health in three ways.

First, we propose to add three new provider specialty types to the list at § 422.116(b)(1), requiring these new specialty types to be subject to network adequacy evaluation. The three new specialty types we propose to add are: (1) clinical psychology, (2) clinical social work, and (3) one category called Prescribers of Medication for Opioid Use Disorder that includes two specialty types: providers with a waiver under section 303(g)(2) of the Controlled Substances Act (CSA) and OTPs. Most of these new specialty types are defined the same way as they are used for the original Medicare program in section 1861(hh) of the Act (defining ''clinical social worker''), § 410.71(d) (defining ''clinical psychologist''), and section 1861(jjj)(2) of the Act (defining ''Opioid Treatment Program''). Section 303(g)(2)of the CSA (21 U.S.C. 823(g)(2)(G)(ii)) establishes which providers have a waiver and we do not believe a definition in the MA regulations at 42 CFR part 422 is necessary.

Our current regulations, at § 422.116(a)(2) specify 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. Therefore, as part of the proposed changes to our list of provider specialty types under § 422.116(b)(1), we are proposing base time and distance standards and minimum number of in-person providers in each county type for each new specialty type as follows:

Maximum Time and Distance Standards:

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
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
Clinical Social Work	20	10	30	20	50	35	75	60	125	110
Prescribers of Medication for Opioid Use Disorder (including MOUD Waivered Providers and/or OTPs)	20	10	30	20	50	35	75	60	110	100

Minimum Ratios:

[57] *https://oig.hhs.gov/oei/reports/OEI-02-22-00390.pdf.*

Minimum Ratio	Large Metro	Metro	Micro	Rural	CEAC
Clinical Psychology	0.15	0.15	0.13	0.13	0.13
Clinical Social Work	0.25	0.25	0.22	0.22	0.22
Prescribers of Medication for Opioid Use Disorder (including MOUD Waivered Providers and/or OTPs)	0.03	0.03	0.03	0.03	0.03

In the proposed rule titled ''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 which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (hereinafter referred to as the February 2020 proposed rule), we explained how CMS developed the base time and distance standards and the minimum provider requirements used in § 422.116 (85 FR 9094 through 9103). CMS established the current base time and distance standards for the provider and facility types listed in § 422.116 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 further explained that 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 (85 FR 9097). Other than the use of the different and more recent data sources that are identified in this preamble, we followed the same analysis and steps to develop the time and distance standards that we propose to apply to the new behavioral health specialty types.

Further, we explained in the February 2020 proposed rule that CMS determines the minimum number requirement for all provider specialty types 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. This is reflected in § 422.116(e)(2)(i) and (e)(3); the current regulation text addresses how the number of beneficiaries required to cover is calculated and will apply to the proposed new provider specialty types. The minimum ratio is the number of providers required per 1,000 beneficiaries. We developed the minimum ratios that currently appear in § 422.116 using various 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, and AMA data on physician productivity. In developing the proposal here to add new specialty types subject to network adequacy evaluation, we conducted additional research to inform appropriate minimum ratio requirements. We reviewed utilization data among FFS Medicare beneficiaries for the proposed specialty types for 2019 through 2021. We reviewed literature on the prevalence of behavioral health disorders among Medicare beneficiaries and existing models for projecting the needed behavioral health workforce such as the Health Resources and Services Administration's (HRSA) Health Workforce Simulation Model,[58] to inform estimates of the potential demand for behavioral health services. We also reviewed data on the potential supply of behavioral health providers, that is, Medicare-enrolled providers in the Provider Enrollment, Chain, and Ownership System (PECOS),[59] the list of practitioners waivered to provide buprenorphine for the treatment of OUD published by the Substance Abuse and Mental Health Services Administration (SAMHSA),[60] and the list of OTP providers enrolled in Medicare published by CMS.[61] We also sought clinical consultation regarding the types of behavioral health providers that treat Medicare beneficiaries, the service locations in which beneficiaries typically use behavioral health care, and typical patterns of care for accessing medication treatment for opioid use disorder, that is, the use of office-based and OTP-based care. Other than the use of different and more recent data sources as identified in this preamble, we followed the same analysis and steps to develop the proposed minimum provider ratios for these new specialty types.

Second, in order to reinforce regulatory requirements for MA plans on their responsibility to provide access to critical behavioral health care services, we propose to amend the list of health care providers in the existing access to services standards at § 422.112(a)(1)(i) to include that the network must also include providers that specialize in behavioral health services.

Finally, to encourage increased access to telehealth providers in contracted MA networks, § 422.116(d)(5) provides that for certain specialties, MA plans may receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards when the plan includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Medicare FFS claims data shows that telehealth was the second most common place of service for claims with a primary behavioral health diagnosis in 2020. As noted previously, the top provider specialty types to provide certain outpatient behavioral services to beneficiaries in that year included psychiatrists, clinical social workers, nurse practitioners, and clinical psychologists. Additionally, previous input from stakeholders discussed the importance of access to telehealth services specific to behavioral health in expanding access to care.

[58] *https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand/behavioral-health.*

[59] *https://pecos.cms.hhs.gov/pecos/login.do#headingLv1.*

[60] *https://www.samhsa.gov/medication-assisted-treatment/find-treatment/treatment-practitioner-locator.*

[61] *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers.*

Based on these considerations, we also propose to add all the new behavioral health specialty types to the list at § 422.116(d)(5) of the specialty types that that will receive the credit if the MA organization's contracted network of providers includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, for covered services.

We welcome comment on this proposal.

3. Behavioral Health Services in Medicare Advantage (MA) (§§ 422.112 and 422.113)

In addition to ensuring that there are specific types of providers in behavioral health specialties accessible within certain parameters in an MA organization's network of providers, it is important to ensure that access to these services is available for enrollees as part of overall delivery and coordination of services. CMS recognizes that knowing where to go to receive behavioral health care services is key to ensuring accessibility to those services. While CMS requires MA organizations to maintain publicly available resources, such as the provider directory, in order to help enrollees access care, we acknowledge that such resources may not always be sufficient to connect enrollees with the services to which they are entitled.

CMS also acknowledges that situations may arise when a behavioral health services provider and an enrollee are not a good fit, and the enrollee needs assistance finding a different provider. Further, when a provider leaves the network, enrollees could experience an interruption in services. Timely provision of care is important with respect to behavioral health outcomes, and with the following proposals, we seek to ensure that enrollees who need behavioral health services are able to access them in a timely manner.

Section 1852(d)(1)(A) of the Act requires MA organizations to make benefits under the plan available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits. To ensure MA enrollees have access to their services that is consistent with the requirements of the statute, CMS proposes to use our authority under section 1856(b)(1) of the Act to adopt standards to implement section 1852(d)(1)(A) of the Act to ensure that access to behavioral health services is prioritized appropriately in the Part C program. CMS proposes to advance this goal by adding behavioral health services to the types of services for which MA organizations must have programs in place to ensure continuity of care and integration of services at § 422.112(b)(3). First, we propose to revise § 422.112(b)(3) to include behavioral health services by adding the phrase, ''and behavioral health services'' after the words ''community-based services'' at the end of § 422.112(b)(3). CMS believes that this proposed change to include behavioral health care services among the services for which MA organizations must have a care coordination program in place will help close the equity gap for enrollees in coordinated care plans. This proposed change would ensure that behavioral health care services are included as part of the enrollee's care coordination.

Next, CMS proposes to codify the agency's interpretation of section 1852(d)(3)(B) of the Act which is used to determine a condition that qualifies as an ''emergency medical condition'' for purposes of carrying out the requirements of section 1852(d)(1)(E) of the Act. Section 1852(d)(1)(E) of the Act requires MA organizations to reimburse a provider for emergency services without regard to prior authorization or the emergency care provider's contractual relationship with the MA organization.

Currently, under § 422.113(b)(1)(i), an ''emergency medical condition'' is defined as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in serious jeopardy to the health of the individual or their unborn child, serious impairment to bodily function, or serious dysfunction of any bodily organ or part; this regulatory definition generally mirrors the statutory definition in section 1852(d)(3)(B) of the Act. However, the definition does not explicitly address that its criteria extends to conditions both physical and mental. CMS interprets the scope of the definition to pertain to both physical and behavioral health conditions when those conditions meet the prudent layperson standard discussed in § 422.113(b)(1)(i), consistent with the statute.

For example, one could reasonably be expected to cause serious injury (or death) to oneself if one's behavioral health condition results in a suicide plan, attempt, other suicidal behavior, or other forms of serious self-harm; CMS believes such cases are sufficient to satisfy the prudent layperson standard, therefore immediate emergency medical intervention must be provided without regard to prior authorization or the emergency care provider's contractual relationship with the organization, consistent with the requirements of section 1852(d)(1)(E) of the Act.

It is important to ensure that MA organizations and affected stakeholders interpret the definition of ''emergency medical condition'' found in § 422.113(b)(1)(i) in the same manner as CMS. Therefore, in an effort to mitigate the possibility that an applicable emergency medical condition, such a qualifying mental health condition, could be inadvertently excluded from the requirements and enrollee protections in § 422.113 due to misinterpretation by an MA organization or entities acting on its behalf, CMS proposes to add language to our regulations that will definitively clarify that an emergency medical condition can be physical or mental in nature. This interpretation and position on what § 422.113 means and requires will guide our enforcement of the regulation. MA organizations, providers and enrollees must comply with this interpretation of the regulation and doing so will assure that MA enrollees receive medically necessary services in a medical emergency.

At § 422.113(b)(1)(i), CMS proposes to amend the regulation by inserting, ''mental or physical,'' after the word ''condition'' and before the word ''manifesting.'' This proposed revision would ensure that emergency medical conditions are easily interpreted as such, thereby prohibiting the use of prior authorization when required and guaranteeing that coverage is provided by the MA organization, consistent with the statute. This will ensure that enrollees have access to emergency behavioral health services in parity with access to other medical emergency services.

We solicit comment on this proposal, and thank commenters in advance for their input on our proposed regulatory revisions.

4. Medicare Advantage (MA) Access to Services: Appointment Wait Time Standards (§ 422.112)

CMS solicited public comment through the RFI that appeared in the January 2022 proposed rule regarding the challenges that exist with accessing behavioral health providers for MA enrollees and how to resolve issues with building adequate behavioral health networks within MA plans. The responses to this RFI included requests that CMS consider strengthening network adequacy standards and improving access to care and services

for enrollees by establishing requirements for appointment wait times for behavioral health services. We also heard that beneficiaries experience barriers to treatment for behavioral health conditions, including opioid use disorder.

Section 1852(d) of the Act requires MA plans that use provider networks, make covered benefits available and accessible to enrollees in the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits, and that medically necessary care must be available and accessible 24 hours a day and 7 days a week. The MA regulation at § 422.112 includes requirements and standards to ensure that MA organizations that offer coordinated care plans, which generally use networks of providers, meet the statutory requirements. Under these rules, MA organizations must ensure that all covered services are made available and accessible to enrollees by the plan's designated provider network. Furthermore, MA organizations are required under § 422.112(a)(6)(i) to maintain written standards that require timely access to care for enrollees which meet or exceed those established by CMS. Timely access to care and member services within a plan's provider network must be continuously monitored to ensure compliance with these standards, and the MA organization must take corrective action as necessary. CMS has provided guidelines for MA organizations in the Medicare Managed Care Manual (MMCM), Chapter 4, ''Benefits and Beneficiary Protections,'' section 110.1.1,[62] regarding provider network standards. That guidance includes directions that MA organizations make their timeliness standards known to network providers (which is necessary in order to ensure that providers in the network comply with MA plan's written standards) and that the MA organization should consider an enrollee's need for the services and common waiting times in the community. In particular, the Manual provides examples of appointment wait times for certain primary care services, based on the type of services and level of need: (1) urgently needed services or emergency—immediately; (2) services that are not emergency or urgently needed, but requires medical attention—within 1 week; and (3) routine and preventive care—within 30 days.

The 2022 CMS Behavioral Health Strategy [63] describes CMS' goals to increase and enhance access to equitable behavioral health care services for people with behavioral health care needs. To support these goals, CMS is committed to strengthening our requirements for MA organizations to ensure beneficiaries can access needed behavioral health care services similar to how they access needed physical health services. Therefore, we propose to codify appointment wait times as standards for primary care services that are the same as the appointment wait times described in the Manual and to extend those standards to behavioral health services. These new minimum appointment wait time standards would be added to the existing requirement that MA organizations establish written policies for the timeliness of access to care and member services so that MA organizations must have appointment wait times that meet or exceed the standards we propose here.

Behavioral health services include both mental health services and substance use disorder services. We remind MA organizations that substance use disorder services include medications for opioid use disorder (MOUD), which is particularly important as opioid-related overdose deaths have spiked during the pandemic,[64] and we have heard from commenters that beneficiaries have experienced barriers to behavioral health treatment. Proposing to codify these wait time standards as discussed by commenters through our RFI, should reduce access barriers to behavioral health treatment for those who need it; and help ensure access to a robust array of practitioners furnishing behavioral health services, including Opioid Treatment Providers who prescribe medications for opioid use disorder.

In addition, the proposal to codify wait time standards for primary care is consistent with the goal to increase access to primary care articulated in HHS' Initiative to Strengthen Primary Care.[65] The National Academies for Science, Engineering, and Medicine (NASEM) Report outlined the importance of ensuring that high-quality primary care is available to every individual and family in every community, particularly those that are underserved. After all, access to primary care practitioners, as opposed to any other practitioner type, is associated with decreased mortality.[66]

We are also seeking comment on alternative specific appointment wait times standards to apply to MA organizations. For example, we are considering, as suggested by a commenter on our RFI, establishing appointment wait time standards that align with those established for qualified health plans, (QHPs) as outlined by CMS in the ''2023 Final Letter to Issuers in the Federally-facilitated Exchanges.'' [67] The appointment wait time standards for QHPs include: Behavioral health appointments must be available within 10 business days, Primary care (routine) must be available within 15 business days; and Specialty care (non-urgent) must be available within 30 business days. Under our proposal, the wait time requirements,, would be applicable to primary care and behavioral health specialty types. We solicit comment whether a more flexible approach would be appropriate, such as requiring MA organizations have these specific appointment wait time standards in their written internal policies but that CMS require MA plans to meet the specific appointment wait time limits for routine or non-emergency services only for a significant portion (for example, 95 percent) of appointments.

This proposed additional requirement to specify maximum wait times for MA enrollees is intended to ensure that MA enrollees are able to access covered services and that MA organizations meet their obligations under section 1852(d) of the Act to make covered benefits available and accessible to enrollees in the plan. Section 1856(b) of the Act authorizes the adoption of standards that are consistent with and to carry out the Part C statute.

We are also considering requiring new and expanding service area applicants to attest to their ability to provide timely access to care consistent with the CMS appointment wait time standards we would add to § 422.112(a)(6)(i). We would implement a new application requirement by adding a new attestation to our ''Part C—Medicare Advantage and 1876 Cost Plan Expansion Application'' that specifically addresses requirements at § 422.112(a)(6)(i). Such an attestation would not be reflected in a specific regulation, however, because

[62] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

[63] *https://www.cms.gov/cms-behavioral-health-strategy.*

[64] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[65] *https://www.hhs.gov/about/news/2022/06/27/fact-sheet-hhs-initiative-to-strengthen-primary-health-care-seeking-public-comment.html.*

[66] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2724393.*

[67] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2023-Letter-to-Issuers.pdf.*

we believe that the requirement at § 422.501(c)(2), that an applicant thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, permits CMS to use an attestation to support the ability of an MA organization to comply with performance requirements. Adequate access to services for MA enrollees is a key consideration.

We solicit comment on our proposal, including whether one or more of the previously described sets of wait time standards would more effectively address our goals of ensuring that MA organizations are meeting timely access standards for primary care and behavioral health services for enrollees, supporting parity between behavioral health and physical health services, and strengthening our requirements for MA organizations to ensure beneficiary protections in access to care. In addition, we solicit comment on whether a specific appointment wait time limit for emergency or urgently needed services is duplicative of the mandatory coverage and access requirements in § 422.113.

C. Medicare Advantage (MA) Network Adequacy: Access to Services (§ 422.112)

Section 1852(d)(1)(A) of the Act establishes that an MA 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 to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits. This is generally implemented at § 422.112(a), which provides that an MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services are available and accessible under the plan. The regulation also includes specific additional requirements for MA organizations offering coordinated care plans related to the availability and accessibility of coverage. In addition, the statute and regulation apply these requirements to all benefits covered by the plan, including both basic and supplemental benefits.

More specifically, section 1852(d)(1)(D) of the Act requires an MA organization to provide access to appropriate providers, including credentialed specialists, for medically necessary treatment and services, as a condition of the MA organization limiting coverage to a specified network of providers. CMS implemented this statutory requirement at § 422.112(a)(1)(i), which provides that the MA organization offering a coordinated care plan must maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. In addition, § 422.112(a)(3) requires that the MA organization provide or arrange for necessary specialty care and arrange for specialty care outside of the plan's provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

Historically, CMS has interpreted these statutory and regulatory requirements to mean that in the event an in-network provider or service is unavailable or inadequate to meet an enrollee's medical needs, the MA organization must arrange for any medically necessary covered benefit outside of the plan provider network at in-network cost sharing for the enrollee. For example, if an enrollee needs OTP services but there is no in-network OTP available, then the MA organization must arrange for the enrollee to go to an out-of-network OTP at in-network cost sharing. In our view, furnishing access out of network with higher cost sharing when the MA plan's network is inadequate or otherwise does not address the medically necessary benefit required by an enrollee is not consistent with section 1852(d)(1) of the Act. Enrollees should not bear a financial burden because of the inadequacy of the MA plan's network. This interpretation is reflected in CMS guidance in section 110.1.1 of Chapter 4 of the MMCM,[68] and CMS has routinely emphasized this interpretation to MA organizations about their obligations whenever the need arises, for example, when an MA organization is undergoing a network change due to a provider termination. Therefore, MA organizations are familiar with the policy and should be applying it in the routine course of operations within their MA plans. It is important that MA organizations ensure adequate access to medically necessary covered benefits for enrollees when the plan network is not sufficient by both arranging or covering the out-of-network benefits and only charging in-network cost sharing for those out-of-network benefits. To reflect this important and well-established enrollee protection in the MA program, we are proposing to amend § 422.112(a)(1) and (a)(3) to more clearly state the scope of the MA organization's obligation to ensure adequate access to medically necessary covered benefits.

Currently, the regulation text at § 422.112(a)(3) does not fully account for the scope of an MA organization's obligations when medically necessary benefits are only accessible out of network in two key ways. First, the regulation text refers to specialty care only, not all medically necessary covered benefits. This oversight does not align with the statutory requirement at section 1852(d)(1)(D) of the Act, which states broadly that the organization must provide access to ''appropriate providers, including credentialed specialists,'' and does not limit the requirement to specialists only. Second, the aspect of maintaining in-network cost sharing when the MA organization arranges for the benefit outside of the network is not clearly stated in § 422.112(a)(3). Therefore, CMS proposes to amend § 422.112 to align more closely with current subregulatory policy and our implementation of section 1852(d) of the Act.

CMS proposes to codify this policy by revising § 422.112(a)(3) and adding new regulatory text to § 422.112(a)(1) to reflect the longstanding policy. Specifically, we propose to move the sentence requiring the MA organization to arrange for out-of-network care currently in paragraph (a)(3) to a new proposed paragraph (a)(1)(iii) and revise and supplement it with additional text to better state the full scope of the current policy. Proposed paragraph (a)(1)(iii) would require MA organizations offering coordinated care plans to arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

CMS currently monitors MA organization compliance with this existing policy through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations alert CMS to any issues with access to care, and CMS may require MA organizations to address these matters if they arise. If finalized, CMS intends to continue these oversight operations to ensure MA organizations' compliance with the proposed regulation.

This proposal to amend § 422.112 codifies the agency's existing interpretation of applicable law and

[68] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

longstanding guidance. CMS has not been made aware of any issues of MA organization non-compliance with this policy and, as such, believes that MA organizations have been complying with this longstanding guidance. Therefore, the proposed amendment to § 422.112 would not impose new information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements), and we have not provided burden estimates in the Collection of Information section of this proposed rule. In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

We solicit comment on this proposal, including on the accuracy of our assumptions regarding information collection requirements and regulatory impact.

D. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

As provided in section 1852(d) of the Act and discussed in section 110.1.2.1 of Chapter 4 of the MMCM, MA organizations have considerable discretion to select the providers with whom to contract in order to build high-performing, cost effective provider networks.[69] This flexibility is also apparent in how CMS is prohibited by section 1854(a)(6)(B)(iii) of the Act from requiring MA organizations to contract with a particular provider. Under our current regulations, MA organizations are able to make changes to these networks at any time during the contract year, as long as they continue to furnish all Medicare-covered services in a non-discriminatory manner, meet established access and availability standards and timely notice requirements, and ensure continuity of care for enrollees. Thus, an MA organization may terminate providers from its network during the plan year, which could impact enrollees who are patients of those providers. CMS requires notification to MA enrollees when a provider network participation contract terminates. Most notably, CMS's disclosure regulations at § 422.111(e) require MA organizations to make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. Additionally, § 422.111(e) requires that when a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified. CMS established these enrollee notification requirements at § 422.111(e) over 22 years ago in the ''Medicare Program; Medicare+Choice Program'' final rule with comment period, which appeared in the **Federal Register** on June 29, 2000 (65 FR 40170) (hereinafter referred to as the June 2000 final rule). The MA program and its policies have evolved considerably since the inception of § 422.111(e). Therefore, CMS is proposing to revise this particular disclosure requirement by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS is also proposing to revise § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.

First, we propose to clarify the regulatory text at § 422.111(e) regarding whether the provider contract termination was for cause or without cause. The regulation currently requires that the MA organization must make a good faith effort to notify enrollees at least 30 calendar days before the termination effective date, irrespective of whether the termination was for cause or without cause. This last clause does not consider § 422.202(d)(4), which outlines the timeframe requirement for suspension or termination of an MA organization's contract with a provider. An MA organization and a contracted provider are required by § 422.202(d)(4) to provide at least 60 days written notice to each other before terminating the contract without cause. Consequently, because MA organizations are provided at least a 60-day notice of any no-cause provider contract termination, MA organizations should be able to timely meet a CMS established enrollee notification requirement that provides the MA organization a period of time that is less than 60 days to notify enrollees of the no-cause provider contract termination. Provider contract terminations that are for-cause, however, do not have an equivalent notification requirement as exists at § 422.202(d)(4) for MA organizations and contracted providers, which means that for-cause provider contract terminations could potentially occur with little notice or without any notice at all. In this case, it may not always be possible for the MA organization to notify enrollees in a reasonable amount of time before the provider contract termination effective date. Thus, we will preserve the phrase ''good faith effort'' for enrollee notifications for for-cause provider contract terminations regarding the proposed timeframes. Under our proposal, the ''good faith effort'' standard would apply to the timing component for for-cause provider contract terminations. However, we propose to remove ''good faith effort'' for no-cause provider contract terminations. We believe that when an MA organization's contracted provider network changes, these enrollee notifications are essential for updating enrollees who are patients of the terminating providers. If an enrollee's provider is dropped from their network during the contract year, the enrollee must be notified so that they can decide how to proceed with the care they are receiving from that provider. By limiting the ''good faith effort'' standard to the timing of for-cause provider contract terminations, we make it clear that issuing the notification to enrollees is a requirement that all MA organizations must follow without exception, but in the case of for-cause provider contract terminations, MA organizations must make a good faith effort to notify enrollees of the termination within the proposed timeframes.

Next, we propose to add new provisions to § 422.111(e) to address provider contract terminations that involve behavioral health providers. For purposes of this proposal, CMS considers various specialty types (both providers and facilities) as fitting the category of behavioral health providers so long as the treatment they furnish to enrollees is about behavioral health; these include but are not limited to psychiatrists, clinical social workers, clinical psychologists, inpatient psychiatric facilities, outpatient behavioral health clinics, OTPs, and MOUD-waivered providers approved by SAMHSA/FDA. As noted in section III.B.1. of this proposed rule, behavioral health is a top priority of both CMS and the broader administration. Specifically, CMS's goal is to improve access to behavioral health services and improve outcomes for people with behavioral health care needs. The CMS Behavioral Health Strategy seeks to remove barriers to care and services.[70] To support these

[69] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

[70] *https://www.cms.gov/cms-behavioral-health-strategy.*

policy goals, using a behavioral health perspective, we have reexamined the MA enrollee notification requirements when a provider contract termination occurs at § 422.111(e).

According to a recent study, because of the ongoing nature of patient/provider relationships, when a provider leaves a plan's network, there is a potential disruption to the patient's treatment plan; this disruption could be especially problematic in the case of behavioral health treatment because this treatment may be longer in duration than that of physical health, and providers and patients are likely to need more time to develop mutual trust.[71] Trusting relationships and continuity in the relationship between the patient and provider have shown to be central for behavioral health recovery, therefore, breaks in these relationships tend to cause patient stress, anxiety, and generally less opportunity to contribute to their treatment plan.[72] Thus, ensuring continuity of care in these situations becomes even more critical. As a consequence, sufficient enrollee notification is needed when a behavioral health provider leaves an MA network. We believe that affected enrollees need ample time to make decisions that may determine the trajectory of their behavioral health treatment. They may wish to continue seeing the terminated provider with whom they have already established a secure, comfortable relationship (potentially with higher out-of-network cost sharing), they may switch to a new provider in the network (forcing them to start a new relationship), or they may choose to stop treatment altogether (which could be detrimental to their health or perhaps fatal in the case of patients with suicidal ideation). Regardless of what action the enrollee takes, however, the enrollee needs to know that their behavioral health provider is leaving their plan's network prior to the contract termination date.

A similar case is made for terminating primary care providers both due to the fact that behavioral health services are often offered by primary care providers and the foundational role primary care providers play in an individual's overall health. According to the American Academy of Family Physicians, up to 75 percent of primary care visits include aspects of behavioral health.[73] Primary care is foundational because it integrates services to meet the patient's health needs throughout a lifetime, including key elements such as health promotion, disease prevention, treatment, rehabilitation, and palliative care.[74] Furthermore, CMS believes that the importance of a patient's relationship with their primary care provider is likely higher in managed care situations, such as MA, where referrals to specialists are often dependent on the primary care provider. Therefore, similar to behavioral health, continuity of care is essential, and sufficient enrollee notification is needed when a primary care provider leaves an MA network. For these reasons, we are proposing more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. We expect positive impacts associated with improving communication about provider terminations from MA networks, including providing more time to MA enrollees with behavioral health conditions to make informed decisions about the future of their behavioral health treatment after their provider leaves their network. Enrollee benefits would result from increased enrollee protections when unexpected primary care and behavioral health network changes occur, and we would also expect to see benefits for providers and facilities who keep their patients informed if they are leaving their MA plan's network.

To address the aforementioned concerns surrounding unexpected changes in MA primary care and behavioral health provider networks, we are proposing to add specific enrollee notification requirements for these types of provider contract terminations. Our proposal has three key aspects. We first propose to add behavioral health providers to the current requirement at § 422.111(e) that all enrollees who are patients of a terminating primary care provider must be notified (not just those enrollees who are patients seen on a regular basis by the terminating provider, which is the case for all other specialty types), and expand the scope of this requirement to refer to all enrollees who have ever been patients of these terminating primary care or behavioral health providers (not just current patients). This addition would be reflected at proposed new paragraph (e)(1)(iii). Next, at proposed new paragraph (e)(1)(ii), we propose to require MA organizations to provide notice to enrollees at least 45 calendar days before the termination effective date for contract terminations that involve a primary care or behavioral health provider, which is longer than the 30-day standard for all other specialty types. Finally, we propose to require both written and telephonic notice for contract terminations that involve a primary care or behavioral health provider at new proposed paragraph (e)(1)(i), while only written notice is required for all other specialty types. We are proposing that both types of notice need to be provided at least 45 calendar days before the termination effective date. For the telephonic notice, we propose that the first telephone call be made to the enrollee at least 45 calendar days in advance. Under our proposal here, the MA organization would be required to continue attempting to reach the enrollee by telephone to provide notice of the termination of the provider from the network. We are not proposing a specific number of attempts required by the MA organization when they reach out to the enrollee by telephone and the call goes unanswered, but we are soliciting comment from MA organizations on how many telephonic attempts they believe are reasonable in this circumstance (for example, 1–5, 6–10, 11–15). To help inform our proposal, we are requesting qualitative feedback based on any MA organization's actual experience providing enrollees telephonic notice of primary care and behavioral health provider contract terminations.

These new proposed requirements for MA organizations providing enrollees notice of primary care and behavioral health provider contract terminations are intended to raise the standards for the stability of enrollees' primary care and behavioral health treatment. If finalized, these requirements would require MA organizations to notify all current enrollees who have ever been patients of the primary care or behavioral health provider or providers leaving their plan's network (regardless of whether these enrollees are patients currently seen on a regular basis, as that standard is established in proposed new paragraph (e)(2)(iii)), give enrollees more notice (and therefore more time) to decide how to proceed with their course of treatment, and provide enrollees with two different means by which they receive the notice from their MA organization. These strengthened enrollee notification requirements for primary care and behavioral health provider contract terminations would generally increase enrollee protections when MA network changes occur. As discussed earlier, continuity of care is essential for both primary care and

[71] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785383.*

[72] *https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-017-2719-9.*

[73] *https://www.aafp.org/pubs/fpm/issues/2021/0500/p3.html#fpm20210500p3-b1.*

[74] *https://www.who.int/health-topics/primary-health-care#tab=tab_1.*

behavioral health, and consequently, adequate communication to enrollees is vital when network changes occur, so that patients of any terminating primary care or behavioral health providers can decide how to proceed with their course of treatment. By receiving adequate notice of the terminations, enrollees will be able to make an informed decision on how to proceed with their care and have more time to potentially locate and establish a relationship with a new provider. Thus, enrollees are protected from any undue harm that may result from an unexpected provider contract termination involving their primary care or behavioral health provider (for example, sudden lack of medication, psychotic episodes, suicide). The proposed enrollee notification requirements are a positive step in the context of our policy for MA provider contact terminations.

Under our proposal, MA organizations will continue to be required to provide written notice at least 30 days before the termination effective date of a termination of a contracted provider that is not a primary care or behavioral health provider to all enrollees who are patients seen on a regular basis by the terminating provider. We also propose to codify at § 422.111(e)(2)(iii) a definition of the phrase ''enrollees who are patients seen on a regular basis by the provider whose contract is terminating.'' CMS currently has sub-regulatory guidance in section 110.1.2.3 of Chapter 4 of the MMCM that defines this term as enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated, also called ''affected enrollees.'' [75] As this guidance has been in place since 2016, and based on various MA organization inquiries we have received asking how CMS defines ''regular basis,'' we believe the majority of MA organizations have come to adopt this CMS standard and use it routinely as they determine which enrollees to notify when provider contract terminations occur, in order to comply with § 422.111(e). Therefore, we propose to codify this definition at proposed § 422.111(e)(2)(iii).

The requirements for contract terminations that involve specialty types other than primary care or behavioral health (written notice only, at least 30 calendar days before the termination effective date, and to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating) would be set forth at new proposed § 422.111(e)(2). This provides a clear distinction for MA organizations between CMS's enrollee notification requirements for contract terminations that involve a primary care or behavioral health provider (at new proposed paragraph (e)(1)) and all other provider contract terminations. We reiterate that the beginning proposed revised regulatory text at § 422.111(e) also distinguishes between no-cause and for-cause provider contract terminations, with the former scenario prompting a requirement for MA organizations to provide the enrollee notifications and the latter requiring MA organizations to make a good faith effort to notify enrollees within the required timeframes. Regardless, whenever an MA organization notifies enrollees about a provider contract termination (whether it is with or without cause), CMS proposes that MA organizations must follow these new requirements outlined at proposed paragraphs (e)(1) and (2).

Finally, regarding the content of the provider termination notice, CMS's regulation at § 422.2267(e)(12) currently provides that the Provider Termination Notice is a required model communications material through which MA organizations must provide the information required under § 422.111(e). CMS has provided additional guidance regarding the content of the provider termination notice in section 110.1.2.3 of Chapter 4 of the MMCM.[76] Similar to the definition of ''affected enrollees,'' these best practices have been in our guidance since 2016, thus we believe the majority of MA organizations likely already follow them as they develop the content of their provider termination notices. Therefore, we propose to codify the best practices for provider termination notices at § 422.2267(e)(12). Specifically, we propose to make these requirements for the content of MA organizations' provider termination notices and also require MA organizations to include additional pieces of information in the notice.

First, at proposed § 422.2267(e)(12)(ii)(A), we are proposing that the provider termination notice must inform the enrollee that the provider will no longer be in the network and the date the provider will leave the network. We have modeled this proposed regulatory text after the established precedent for the equivalent notice requirement for the Non-renewal Notice model communications material as provided at § 422.2267(e)(10)(ii)(A) (we refer readers to section III.P. of this proposed rule for our proposal to amend paragraph (e)(10) to make the Non-renewal Notice a standardized communications material). Next, we propose to codify a requirement to include the information currently described in the best practices guidance in Chapter 4 of the MMCM at proposed § 422.2267(e)(12)(ii)(B), (C), and (E), specifically: names and phone numbers of in-network providers that the enrollee may access for continued care (this information may be supplemented with information for accessing a current provider directory, including both online and direct mail options) (at proposed paragraph (e)(12)(ii)(B)); how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider (at proposed paragraph (e)(12)(ii)(C)); and the MA organization's call center telephone number, TTY number, and hours and days of operation (at proposed paragraph (e)(12)(ii)(E)). For proposed paragraph (e)(12)(ii)(B) and (C), we are proposing to use the same description for the relevant content that is currently found in CMS's guidance in Chapter 4 of the MMCM. However, for proposed paragraph (e)(12)(ii)(E), instead of using the existing Chapter 4 language (''customer service number(s) where answers to questions about the network changes will be available''), we have chosen to model the proposed regulatory text after the established precedent of a requirement for the Non-renewal Notice at § 422.2267(e)(10)(ii)(H). We believe that the proposed new language of ''call center telephone number, TTY number, and hours and days of operation'' is more inclusive as it encompasses not just the customer service number but also the TTY number and operation times.

In addition, at proposed § 422.2267(e)(12)(ii)(D), we are proposing that the provider termination notice must provide information about the Annual Coordinated Election Period (AEP) and the MA Open Enrollment Period (MA–OEP) and must explain that an enrollee who is impacted by the provider termination may contact 1–800–MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period (SEP), as specified in § 422.62(b)(26), based on the individual's unique circumstances and consistent with existing parameters for this SEP. We solicit comment on our proposal to consider an enrollee who is

[75] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

[76] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

impacted by a provider contract termination to be someone who is experiencing an exceptional condition, as specified in § 422.62(b)(26), and therefore eligible for this SEP. We also solicit comment on alternative approaches; specifically, the adoption of a new SEP for this type of provider contract termination, with explicit standards for when termination of a provider from the network should serve as a basis for SEP eligibility.

The last proposal we are making regarding the provider termination notice requirements at § 422.2267(e)(12) concerns CMS's requirements for the telephonic notice that we are proposing MA organizations must provide to enrollees at least 45 days in advance of a primary care or behavioral health provider contract termination. Specifically, at proposed § 422.2267(e)(12)(iii), we propose that the telephonic notice of provider termination specified in proposed § 422.111(e)(1)(i) must relay the same information as the written provider termination notice as described in paragraph (e)(12)(ii) of § 422.2267. We believe that requiring the MA organization to communicate the same information on the primary care or behavioral health provider contract termination through two different channels—a written letter and a telephone call—will ensure that affected enrollees receive the information they need to decide how to proceed with their current course of treatment. The telephonic communication will reiterate the change occurring in the plan's network and the options the enrollee has moving forward in the absence of their current provider.

The provider termination notice is a model communications material which, per § 422.2267(c), is created by CMS as an example of how to convey enrollee information. When drafting this required communications material, MA organizations must: (1) accurately convey the vital information in the required material to the enrollee, although the MA organization is not required to use the CMS model material verbatim; and (2) follow CMS's order of content, when specified (see § 422.2267(c)(1) and (2)). While the regulation currently identifies the provider termination notice as a model communications material, CMS has not yet developed the model document for MA organizations to use. Rather, MA organizations have been expected to follow the current guidance in section 110.1.2.3 of Chapter 4 of the MMCM.[77] Given that we are now proposing new regulatory requirements for the content of these provider termination notices (including codifying existing best practices provided in CMS's guidance), CMS intends to create a model document for the provider termination notice that contains the requirements at proposed § 422.2267(e)(12), if finalized. We believe that this model document would be welcomed by MA organizations as it will provide a useful template that MA organizations may follow when developing their own provider termination notices. Our proposal for § 422.2267(e)(12) specifies the required information, and the model document that CMS intends to develop would reflect this information as well. In addition, when developing provider termination notices, all MA organizations must follow the general communications materials and activities requirements outlined at § 422.2262 and the standards for required materials and content at § 422.2267(a).

Regarding compliance monitoring for the regulatory amendments proposed here, CMS currently monitors MA organization compliance with the existing policies at §§ 422.111(e) and 422.2267(e)(12) through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations alert CMS to any issues with enrollees that did not receive adequate notice of a provider contract termination, and CMS may require MA organizations to address these matters if they arise. If finalized, CMS intends to continue these oversight operations to ensure MA organizations' compliance with the proposed regulation. In accordance with § 422.2261(c)(2), CMS may require submission or submission and approval of communications materials prior to use if additional oversight is warranted as determined by CMS based on feedback such as complaints or data gathered through reviews. This is to ensure the information being received by enrollees is accurate. Furthermore, § 422.2261(d)(1) and (3) establish that CMS reviews materials to ensure compliance with all applicable requirements under §§ 422.2260 through 422.2267 and that CMS may determine, upon review of such materials (either prospective or retrospective), that the materials must be modified, or may no longer be used. Therefore, CMS reserves the right to review any MA organization's provider termination notice if we receive complaints or other information signifying that the notice warrants additional oversight to ensure compliance with CMS regulations for provider termination notices at §§ 422.111(e) and 422.2267(e)(12). If CMS does exercise its authority under § 422.2261(c) to review an MA organization's provider termination notice, per § 422.2261(d)(1) and (3), CMS will review the notice to ensure compliance with the applicable regulations and, as a result, may require the MA organization to modify the notice or no longer use it.

In summary, CMS is proposing to revise: (1) § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur; and (2) § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination. We solicit comment on these proposals.

E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138)

1. Introduction

A majority of MA plans are coordinated care plans, which is defined at § 422.4(a) as a plan that includes a network of providers that are under contract or arrangement with an MA organization to deliver the benefit package approved by CMS. CMS regulations at § 422.202(b) require that each MA organization consult with network providers on the organization's medical policy, quality improvement programs, medical management procedures, and ensure that certain standards are met. For example, coordinated care plans must ensure that practice guidelines and utilization management guidelines are based on reasonable medical evidence or a consensus of health care professionals in the particular field; consider the needs of the enrolled population; are developed in consultation with contracting physicians; and are reviewed and updated periodically. Further, these guidelines must be communicated to providers and, as appropriate, to enrollees.

Coordinated care plans are designed to manage cost, service utilization, and

[77] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

quality by ensuring that only medically necessary care is provided. This is done in part through the use of utilization management tools, including prior authorization, expressly referenced at section 1852(c)(1)(G) and (c)(2)(B) of the Act. These tools are designed to help MA plans determine the medical necessity of services and minimize the furnishing of unnecessary services, thereby helping to contain costs and protect beneficiaries from receiving unnecessary care. Additionally, section 1852(g)(1)(A) of the Act states that MA plans shall have a procedure for making determinations regarding whether an enrollee is entitled to receive a health care service and that such determinations must be made on a timely basis; that provision applies to both prior authorization determinations and to post-service decisions about coverage and payment.

In addition, CMS regulations at § 422.101(a) and (b) require that MA plans provide coverage of all basic benefits (that is, services covered under Medicare Parts A and B, except hospice care and the cost of kidney acquisitions for transplant) and that MA plans must comply with Traditional Medicare national coverage determinations (NCDs) and local coverage determinations (LCDs) applicable in the MA plan's service area.[78] In recent years, CMS has received feedback from various stakeholders, including patient groups, consumer advocates, providers and provider trade associations that utilization management in MA, especially prior authorization, can sometimes create a barrier to patients accessing medically necessary care. Stakeholder feedback has included concerns about the quality of MA plans' prior authorization decisions (for example, coverage denials being made by plan clinicians who do not have expertise in the field of medicine applicable to the requested service) and process challenges (for example, repetitive prior approvals for needed services for enrollees that have a previously-approved plan of care).

In addition, in April 2022, the Office of the Inspector General (OIG) released a report[79] titled, ''Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care,'' which summarized the results of a study by the OIG of MA plan denials of requests for prior authorization of services. The OIG found that some prior authorization requests were denied by MA plans, even though the requested services met Medicare coverage guidelines. In other cases, the OIG found that prior authorization requests were inappropriately denied due to errors that were likely preventable through process or system changes by MA organizations. Citing a concern that such inappropriate denials may prevent or delay beneficiaries from receiving medically necessary care, the OIG recommended that CMS: (1) issue new guidance on the appropriate use of MA organization clinical criteria in medical necessity reviews; (2) update its audit protocols to address the issues related to MA organizations' use of clinical criteria and/or examining particular service types; and (3) direct MA organizations to take steps to identify and address vulnerabilities that can lead to manual review errors and system errors.[80]

CMS understands that utilization management tools are an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. In light of the feedback we have received from stakeholders and the findings in the OIG report, however, we have concluded that certain guardrails are needed to ensure that utilization management tools are used, and associated coverage decisions are made, in ways that ensure timely and appropriate access to medically necessary care for beneficiaries enrolled in MA plans. We propose to clarify requirements for the coverage criteria that MA plans use when making medical necessity determinations. We are also proposing additional beneficiary protection requirements in order to improve care continuity and integration of health care services and to increase plan compliance responsibilities with regards to utilization management policies. Our proposals here would interpret and implement the requirements in section 1852 regarding the provision and coverage of services by MA plans and are therefore proposed under our authority in section 1856 of the Act to adopt standards to carry out the Part C statute and MA program.

As originally stated in the June 2000 final rule (65 FR 40207), MA organizations must cover all Part A and B benefits, excluding hospice services and the cost of kidney acquisitions for transplant, on the same conditions that items and services are furnished in Traditional Medicare. This means that MA organizations may not limit coverage through the adoption of policies and procedures—whether those policies and procedures are called utilization management and prior authorization or the standards and criteria that the MA organization uses to assess and evaluate medical necessity—when those policies and procedures result in denials of coverage or payment where the Traditional Medicare program would cover and pay for the item or service furnished to the beneficiary. In addition, this means that limits or conditions on payment and coverage in the Traditional Medicare program—such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant NCDs and LCDs, and other substantive conditions—apply to set the scope of basic benefits as defined in § 422.100(c).

MA organizations have flexibility to furnish and cover services without meeting all substantive conditions of coverage in Traditional Medicare, but that flexibility is limited to and in the form of supplemental benefits. As stated in the June 2000 final rule, MA organizations' flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the MA program. If Traditional Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Traditional Medicare benefits (that is, basic benefits) component of an MA plan. MA organizations may cover the same service when the conditions are not met, but these benefits would then be defined as supplemental benefits within the scope of §§ 422.100(c)(2) and 422.102 and must be included in the supplemental benefits portion of the MA plan's bid. For example, when services are furnished by a type of provider other than the type of provider who may furnish the service in Traditional Medicare, those services are supplemental benefits. In this rule, we are proposing policies that would provide less flexibility for MA organizations to deny or limit coverage of basic benefits than provided in the 2000 final rule. However, as provided by section 1852(a)(3) of the Act and reflected in §§ 422.100(c)(2) and 422.102, MA plans may cover benefits beyond what is covered (and when it is covered) under Traditional Medicare by offering supplemental benefits. Our proposal is primarily directed at ensuring that minimum coverage

[78] The terms ''Traditional Medicare'' and ''Original Medicare'' are used interchangeably throughout this section and both mean the Medicare Fee-For-Service program.

[79] *https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.*

[80] *https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf,* pg. 3.

requirements are met and that MA plans do not deny or limit coverage of basic benefits; we are not proposing to limit the scope of permissible supplemental benefits, but our proposal would apply certain requirements for the use of utilization management (UM) for all covered benefits as discussed in section III.E. of this proposed rule.

In this proposed rule, we clarify acceptable cost-effective utilization management approaches for MA organizations to use in the context of the new proposed requirements. These clarifications aim to ensure access to medically necessary care while maintaining MA organizations' ability to apply utilization management that ensures clinically appropriate care. Additionally, our proposals address substantive rules regarding clinical coverage criteria for basic benefits and how they interact with utilization management policies, including revisions to existing regulations and adopting new regulations to ensure that MA enrollees receive the basic benefits coverage to which they are entitled and to ensure appropriate treatment of a benefit as a basic benefit or supplemental benefit for purposes of the bid under § 422.254. We solicit comment on whether our proposed regulatory provisions sufficiently address the requirements and limits that we describe in the preamble.

2. Coverage Criteria for Basic Benefits

In interpreting requirements involving coverage criteria, whether used for prior authorization or post-service payment, CMS has a longstanding policy, discussed in sub-regulatory guidance (section 10.16 of Chapter 4 of the MMCM), that MA plans must make medical necessity determinations based on internal policies, which include coverage criteria that are no more restrictive than Traditional Medicare's national and local coverage policies and approved by a plan's medical director. In light of the previously discussed feedback and the OIG recommendation that we issue new guidance on the appropriate use of MA organization clinical criteria in medical necessity reviews, we propose to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than Traditional Medicare. Section 1862 of the Act requires original Medicare benefits to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Thus, in order to meet the statutory requirements at section 1852(a)(1) of the Act, which requires MA plans to cover A and B services, MA plan coverage criteria must do the same. We also are proposing to amend § 422.101(b) and (c) to clarify the obligations and responsibilities for MA plans in covering basic benefits.

Section 1852(a)(1) of the Act and CMS regulations at § 422.101(a) and (b) require all MA organizations to provide coverage of, by furnishing, arranging for, or making payment for, all items and services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. Section 422.101 requires MA organizations to comply with all NCDs; LCDs written by Medicare Administrative Contractors (MACs) with jurisdiction for Medicare claims in the MA organization or plan's service area; and coverage instructions and guidance in Medicare manuals, instructions and other guidance documents unless those materials are superseded by regulations in part 422.

We propose to amend § 422.101(b)(2) by removing the reference to ''original Medicare manuals and instructions'' and clarify that MA organizations must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans, when making coverage decisions. Our proposal is designed to prohibit MA organizations from limiting or denying coverage when the item or service would be covered under Traditional Medicare and continue the existing policies that permit MA organizations to cover items and services more broadly than original Medicare by using supplemental benefits. In proposing this change to § 422.101(b)(2), we are reiterating that limits or conditions on payment and coverage in the Traditional Medicare program—such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant NCDs and LCDs, and other substantive conditions—apply to define the scope of basic benefits. By removing the reference to ''original Medicare manuals and instructions,'' we are not diminishing the content and value that these manuals and instructions provide in interpreting and defining the scope of Part A and Part B benefits. MA organizations should follow and comply with CMS's interpretation of Medicare laws and coverage requirements as reflected in the manuals, guidance and instructions issued by CMS, which is the agency with the applicable expertise and authority for Medicare. The proposed revision to § 422.101(b)(2) clarifies that statutes and regulations that set the scope of coverage in the Traditional Medicare program are applicable to MA organizations in setting the scope of basic benefits that must be covered by MA plans. We also propose to refer in § 422.101(b)(2) to specific Medicare regulations that include coverage criteria for Part A inpatient admissions, Skilled Nursing Facility (SNF) care, Home Health Services and Inpatient Rehabilitation Facilities (IRF) as examples of general coverage and benefit conditions in Traditional Medicare that apply to basic benefits in the MA program. The list of Medicare regulations referred to is not exhaustive and provides examples of substantive coverage and benefit conditions that apply to MA. In addition, we are also proposing to revise the current provision that states that Traditional Medicare coverage rules apply unless superseded by regulations in this part. We propose to revise that aspect of § 422.101(b)(2) to refer to laws applicable to MA plans in order to avoid implying that a Part 422 regulation could supersede an applicable statute.

The existing rule at § 422.101(c), which states that MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of post-hospital SNF care in the absence of the prior qualifying hospital stay is an example of a special rule in MA that deviates from coverage criteria articulated in Traditional Medicare. The regulation is based on section 1812(f) of the Act, which authorizes CMS to permit coverage of SNF care without the 3 day qualifying hospital stay in limited circumstances. (68 FR 50847–50848) This rule provides MA organizations the flexibility to cover SNF stays for MA enrollees that would not be otherwise coverable in Traditional Medicare, if the beneficiary had not met the prior qualifying hospital stay of 3 days prior to admission in the SNF. This special rule continues to apply in the MA program; however, we propose to redesignate this rule to paragraph (c)(2) of § 422.101 as part of our proposal to add a heading to § 422.101(c) and to expand the scope of the paragraph. We propose to add the heading ''Medical Necessity Determinations and Special Coverage Provisions'' to § 422.101(c). As such, we propose to reassign the special rule for coverage of posthospital SNF in the absence of the prior qualifying hospital stay as § 422.101(c)(2).The proposed new heading for § 422.101(c), ''Medical Necessity Determinations and Special Provisions,'' signals that paragraph (c) will address medical necessity criteria and special rules that apply to MA basic benefits that do not necessarily conform to coverage rules in Traditional Medicare.

We propose to codify at § 422.101(c)(1)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria that are not specified in § 422.101(b) or (c). This means that when an MA organization is making a coverage determination on a Medicare covered item or service, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies. It is our interpretation that certain utilization management processes, such as clinical treatment guidelines that require another item or service be furnished prior to receiving the requested item or service, would violate the proposed requirements at § 422.101(b) and (c), and thus, would be prohibited under this proposal unless it is specified within the applicable NCD or LCD or Medicare statute or regulation. We note that we are not proposing to revise § 422.136, which authorizes MA plans to use step therapy policies for Part B drugs under certain circumstances; in the next paragraph, we discuss the basis for authorizing step therapy for Part B drugs in § 422.136 in more detail. Clinical criteria that restrict access to a Medicare covered item or service unless another item or service is furnished first, when not specifically required in NCD or LCD, would be considered additional internal coverage criteria that are prohibited under this proposal. When MA plans are allowed to create internal coverage criteria as specified at proposed § 422.101(b)(6), the current evidence in widely used treatment guidelines or clinical literature relied upon to make the coverage determination may recommend clinical treatment guidelines that require another item or service first. As long as the supporting widely used treatment guidelines or clinical literature recommend another item or service first, this would be acceptable under our proposed policy. We discuss the proposal to add § 422.101(b)(6) later in this section of the proposed rule.

In a HPMS memo released August 7, 2018, CMS announced that under certain conditions beginning in contract year 2019, MA plans may use utilization management tools such as step therapy for Part B drugs. In a May 2019 final rule (84 FR 23832), we codified MA organizations' ability to use step therapy for Part B drugs under certain conditions that protect beneficiaries and acknowledged that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs.

We clarified that, with respect to clinical concerns and interference with provider care, step therapy or other utilization management policies may not be used as unreasonable means to deny coverage of medically necessary services or to eliminate access to medically necessary Part B covered drugs. (84 FR 23856) The requirements in the 2019 rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care. Organizations have been and remain subject to the MA regulations and must comply with national and applicable local coverage determinations. Step therapy protocols cannot be stricter than an NCD or LCD with specified step therapy requirements. Thus, this proposal remains consistent with the 2019 rule in that plans must still comply with NCDs and LCDs when developing step therapy programs for Part B drugs.

Finally, in the May 2019 final rule, we did not authorize step therapy practices for Part A or Part B (non-drug) items or services and our proposal here will limit the ability of MA organizations to use such UM policies in connection with non-drug covered items or services that are basic benefits. There are a number of differences with step therapy for Part B drugs and step therapy for non-drug items and services. From a clinical standpoint, there tends to be more than one drug that has demonstrated success in treating a certain disease or condition, and also there are generic alternatives, which is somewhat different than other Part A and B services. Often, there are not head-to-head comparisons between drugs in a certain class of medications, because a non-inferiority study [81] was conducted in order to bring the drug to market. This means that it is not always obvious what the clinically superior drug is for certain diseases or conditions, while there may be a significant difference in pricing. Furthermore, there are several studies [82] demonstrating how increased cost sharing for medications can, in and of itself, reduce patient adherence to those medications.

In addition, the manner in which Part B drugs are purchased and furnished is somewhat different from coverage of non-drug healthcare items and services. Generally, MA organizations pay the provider for both the service of administering a Part B drug and the cost of the drug, but do not directly pay drug manufacturers or suppliers for the cost of the drug. MA organizations may negotiate pricing discounts or rebates with the manufacturer, who is not the entity that directly furnishes the Part B drug to enrollees and who is not ordinarily paid directly by the MA organization for what is furnished to enrollees. As we explained in the May 2019 final rule (84 FR 23858, 23863, and 23869), we believe that § 422.136 can put MA organizations in a stronger position to negotiate lower pharmaceutical prices with drug manufacturers, reducing the cost sharing for the beneficiary. Furthermore, as mentioned previously, studies have demonstrated that increased cost sharing for medications can reduce patient adherence to those medications. Therefore, we are not proposing to revise our current regulations regarding Part B step therapy at this time.

Similar to MACs in Traditional Medicare, we expect MA organizations to make medical necessity decisions by using NCDs, LCDs, and other applicable coverage criteria in Medicare statutes and regulations to determine if an item or service is reasonable, necessary and coverable under Medicare Part A or Part B. In some circumstances, NCDs or LCDs expressly include flexibility that allows coverage in circumstances beyond the specific coverage or non-coverage indications that are listed in the NCD or LCD. For example, an NCD or LCD may state that the item or service can be covered when reasonable and necessary for the individual patient. When deciding whether an item or service is reasonable and necessary for an individual patient, we expect MA organizations to make medically necessary decisions in a manner that most favorably provides access to services for beneficiaries and aligns with CMS's definition of reasonable and necessary in the Medicare Program Integrity Manual, Chapter 13, section 13.5.4. This expectation applies to coverage determinations made before the item or service is provided (pre-certification/prior authorization), during treatment (case management), or after the item or service has been provided (claim for payment). As recommended by the OIG, this proposal clarifies the limited clinical coverage criteria can be applied to basic benefits and reinforces our longstanding policy that MA organizations may only apply coverage criteria that are no more restrictive than

[81] *https://www.fda.gov/media/78504/download.*

[82] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/.*

Traditional Medicare coverage criteria found in NCDs, LCDs, and Medicare laws. We reiterate that this proposal also applies to substantive coverage criteria and benefit conditions found in Traditional Medicare regulations, such as those governing inpatient admissions and transfers to post-acute care settings, which are not governed by NCD or LCD. Therefore, MAOs may only deny a request for Medicare-covered post-acute care services in a particular setting, if the MAO determines that the Traditional Medicare coverage criteria for the services cannot be satisfied in that particular setting. As we will discuss in section III.E.3 in this proposal, this does not restrict an MA organization's ability to use certain utilization management processes, like prior authorization or post claim review, to ensure items and services meet Medicare coverage rules; it simply limits the coverage criteria that an MA organization can apply to deny an item or service during those reviews. We solicit comment about the specificity of the coverage conditions in Traditional Medicare regulations and whether we should consider, and under what circumstances, allowing MA organizations to have internal coverage criteria in addition to requirements in current regulations.

We recognize that there are some Part A or Part B benefits that do not have applicable Medicare NCDs, LCDs, or specific traditional Medicare coverage criteria in regulation for MA plans to follow when making medical necessity determinations. Therefore, we propose at § 422.101(b)(6) that when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. In creating these internal policies, we propose that MA organizations must follow similar rules that CMS and MACs must follow when creating NCDs or LCDs. Specifically, MA organizations must provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations.

Section 1862(l) of the Act requires the Secretary to issue publicly a discussion and explanation of the factors considered in making NCDs, after following a process that affords the public an opportunity to comment prior to implementation. We propose at § 422.101(b)(6) that MA organizations must follow a somewhat similar process when creating internal plan coverage criteria by providing a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. We are not proposing that MA organizations must provide a pre-determination explanation and opportunity for the public to comment on the MA organization's coverage criteria; however, providing a publicly accessible summary of the evidence, a list of the sources of evidence, and an explanation of the rationale for the internal coverage criteria will protect beneficiaries by ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature. This requirement provides further transparency into MA organizations' medical necessity decision making and is consistent with CMS's expectation that MA organizations develop and use coverage criteria in a way that aligns with Traditional Medicare.

We are also proposing at § 422.101(b)(6) a requirement that an MA organization's internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions (such as referring to the Infectious Diseases Society of America for the Treatment of *Clostridium Difficile*[83]) or to determine appropriate level of care (such as the American Society of Addiction Medicine Criteria for placement,[84] continued stay, and transfer or discharge of patients with addiction and co-occurring conditions). Clinical literature that CMS considers to be of high enough quality for the justification of internal coverage criteria include large, randomized controlled trials or cohort studies or all-or-none studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question published in a peer-reviewed journal with clear and consistent results. Evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization, or that does not comply with the standards, as previously described, would not represent proper justification for instituting internal coverage guidelines that would restrict access to care. This evidentiary standard is overall consistent with published frameworks[85] that rank the reliability of different types of studies in the clinical literature. CMS solicits comment on the definition of widely used treatment guidelines and clinical literature that would justify internal coverage criteria used in the absence of NCDs, LCDs, or Traditional Medicare statutes or regulations along with the other requirements proposed in new § 422.101(b)(6)

Medical Necessity Determinations

CMS has longstanding guidance interpreting the obligations of MA organizations when making medical necessity determinations. Per CMS regulations at § 422.112(a)(6)(ii), MA plans must have policies and procedures that allow for individual medical necessity determinations. As a result, an MA organization's coverage rules, practice guidelines, payment policies, and utilization management policies should be applied to make individual medical necessity determinations based on the individual circumstances for the enrollee and item or benefit to be covered. Chapter 4 of the MMCM, section 10.16, provides that MA organizations make coverage determinations that are based on: (1) the medical necessity of plan-covered services based on coverage policies (this includes coverage criteria no more restrictive than traditional Medicare described previously and proposed at § 422.101(b)(6)); (2) where appropriate, involvement of the plan's medical director per § 422.562(a)(4); and (3) the enrollee's medical history (for example, diagnoses, conditions, functional status)), physician recommendations, and clinical notes. We are proposing to codify these existing standards for medical necessity decision making at § 422.101(c)(1)(i) and propose some new requirements to connect medical necessity determinations to our new requirements at § 422.101(b). Therefore, as previously mentioned, we are proposing to codify at § 422.101(c)(1)(i)(A) that MA

[83] Reference: *https://www.idsociety.org/practice-guideline/clostridium-difficile/.*

[84] *https://www.asam.org/asam-criteria.*

[85] (for example, Oxford Centre for Evidence-Based Medicine levels of evidence *https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009andStrengthof RecommendationTaxonomyhttps://www.jabfm.org/content/17/1/59#F1).*

organizations must make medical necessity determinations based on coverage and benefit criteria as defined at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not found in those sources. Second, we propose at § 422.101(c)(1)(i)(B) to require MA organizations to consider whether the item or service is reasonable and necessary under 1862(a)(1) of the Act. We note that this has been a longstanding policy in MA based on how section 1852 of the Act requires MA plans to cover items and services for which benefits are available under original Medicare, however we believe it is important to acknowledge this in the context of MA organization decisions involving medical necessity. Third, we propose to codify existing policy at § 422.101(c)(1)(i)(C) that MA organizations consider the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes. Finally, consistent with current requirements at § 422.562(a)(4), we propose at § 422.101(c)(1)(i)(D) that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate. We solicit comments on when it would be appropriate for the MA organization's medical director to be involved, in light of how § 422.562(a)(4) requires the medical director to be responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity.

Authority for MA organizations to use utilization management policies with regard to basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards to carry out the MA provisions. We believe these proposals will further implement the requirements set forth in section 1852 of the Act and §§ 422.100 and 422.101, which require MA organizations to furnish all reasonable and necessary Part A and B benefits. These proposed requirements for how MA organizations make coverage decisions will ensure that MA organizations provide equal access to Part A and Part B benefits as provided in the Traditional Medicare program; overall our proposals mean that MA organizations will not be able to deny coverage for basic benefits using coverage criteria that is not consistent with coverage criteria in Medicare statutes, regulations, NCDs and LCDs or that is not consistent with the limitations proposed in § 422.101(b)(6).

We affirm that coordinated care plans may continue to include mechanisms to control utilization, such as prior authorization, referrals from a gatekeeper for an enrollee to receive services within the plan, and, subject to the rules on physician incentive plans at §§ 422.208 and 422.210, financial arrangements that offer incentives to providers to furnish high quality and cost-effective care in addition to the coverage criteria that comply with § 422.101(b). We affirm that MA organizations may furnish a given service using a defined network of providers, some of whom may not see patients in Traditional Medicare. Further, we affirm that MA organizations may encourage patients to see more cost-effective provider types than would be the typical pattern in Traditional Medicare (as long as those providers are working within the scope of practice for which they are licensed to provide care and comply with the provider antidiscrimination rules set forth under § 422.205). For instance, MA organizations may offer more favorable cost sharing for certain provider types within their network.

We also stated in the June 2000 final rule that when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, that an MA plan could choose how the covered services will be provided. We are proposing a narrower policy that permits MA organizations to continue to choose who provides Part A and Part B benefits through the creation of their contracted networks, but limits MA organizations' ability to limit when and how covered benefits are furnished when Traditional Medicare will cover different provider types or settings. As a result of the proposal at § 422.101(c)(1)(i), when care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may only deny coverage of the services or setting on the basis of the ordered services failing to meet the criteria outlined in § 422.101(c)(1)(i). (We are proposing to reserve paragraph (c)(1)(ii) to provide flexibility in modifying the limits on MA medical necessity policies in the future.) For example, if an MA patient is being discharged from an acute care hospital and the attending physician orders post-acute care at a SNF because the patient requires skilled nursing care on a daily basis in an institutional setting, the MA organization cannot deny coverage for the SNF care and redirect the patient to home health care services unless the patient does not meet the coverage criteria required for SNF care in §§ 409.30–409.36 and proposed § 422.101(b) and (c).

In order to demonstrate how these policies will apply to actual cases, we discuss these proposed requirements in the context of two case examples that were cited in the OIG report. In the first case, an MA patient was a smoker and had a history of lung nodules and the provider ordered a Computed Tomography (CT) scan of the chest. NCD 220.1 [86] identifies Medicare coverage and limitations for CT scans. In this specific case, the MA organization cited internal clinical criteria that limited CT scans based on the size of nodules and the receipt of chest X-rays. In our proposed policy, the internal criteria applied by the MA organization would be prohibited because there is no provision in the NCD that requires other diagnostic tests, such as a chest X-ray, to be tried before CT scanning is used. In order to appropriately deny this request for a CT scan under our proposed policy, the MA organization would need to identify why the CT scan, as the initial diagnostic test, was not reasonable and necessary based on the medical necessity determination requirements at the proposed 422.101(1)(A) through (D).

In another case, an MA patient had a history of dementia, hypertension and was legally blind due to glaucoma. The patient was admitted to the acute-care hospital for worsening dementia and acute agitation. The acute-care hospital requested that the patient be discharged to a SNF, but the MA organization denied the request based on the MA organization's internal clinical criteria that determined that the patient did not have a need for skilled care. The specific conditions for meeting level of care requirements at a SNF, the criteria for skilled services, and the need for skilled services can be found at 42 CFR 409.30–409.36. The internal clinical criteria used by the MA organization in this case were not identified by the OIG. However, if the internal criteria were not consistent with the criteria listed in §§ 409.30–409.36, it would be prohibited under our proposal. The OIG noted that because the patient required physician supervision and access to physical and occupational therapy, the MA organization should have covered the SNF care requested.

[86] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=176.*

In this proposed rule, we are unable to quantify the impact of these changes on MA organizations because many MA organizations may already be interpreting our current rules in a way that aligns with our proposal. MA organizations may have interpreted our longstanding policy that they cannot apply coverage criteria that are more restrictive than Traditional Medicare national and local coverage policies to mean exactly what we are proposing here: that they may only deny Medicare items or services based on criteria consistent with Traditional Medicare coverage rules. Other MA organizations may have interpreted our current rules to mean that they can use internal policies, like utilization management guidelines, to deny approval for a particular item or service while directing the MA enrollee to different, but clinically appropriate, Medicare-covered item or service. The OIG stated in their report that ''CMS guidance is not sufficiently detailed to determine whether MA organizations may deny authorization based on internal MA organization clinical criteria that go beyond Medicare coverage rules.'' As a result, in this proposal we are making it clear that MA organizations may not deny authorization based on internal MA organization clinical criteria that go beyond Medicare coverage rules or comply with proposed § 422.101(b)(6) addressing standards for when MA internal coverage rules are permissible. However, we are unable to quantify or predict how many MA organizations are currently operating in a manner that conforms with our proposal. We solicit comment from stakeholders on the full scope of this burden.

3. Appropriate Use of Prior Authorization

Except for emergency, urgently needed, and stabilization services (§ 422.113(a)), and out-of-network services covered by MA PPO plans, all services covered by MA coordinated care plans (including MSA network plans, which are coordinated care plans under 422.4(a)(iii)(D)), may be subject to prior authorization. In addition, MA PFFS and MA MSA plans are not permitted to use prior authorization policies or ''prior notification'' policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS or MSA plan in advance that services will be furnished. See § 422.4(a)(2)(i)(B) and (a)(3)(iv). Appropriate prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care. We propose to codify this at new § 422.138(a). Specifically, we are proposing a new § 422.138(a) to provide that a coordinated care plan may use prior authorization processes for basic benefits and supplemental benefits only when the prior authorization processes are consistent with new § 422.138. We propose to use the term ''processes'' to include prior authorization policies and procedures that address any and all aspects of how prior authorization is used by an MA organization in a coordinated care plan. We are also proposing a new § 422.138(b)(1) through (3) to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental benefits is clinically appropriate. This is consistent with longstanding guidance in Chapter 4, section 30.2, of the MMCM (and also stated in the CY 2021 Final Rule [86 FR 5864]) that supplemental benefits must be medically necessary.

We are aware that Special Supplemental Benefits for the Chronically Ill (SSBCI) may be non-primarily health related. Regular supplemental benefits must be medically necessary, but SSBCI need to have a reasonable expectation of improving or maintaining the health or overall function of the enrollee as required at § 422.102(f)(1)(ii)) and discussed in CY2020 Final Rule (85 FR 33796).

To illustrate how these proposed prior authorization policies would work, we discuss an example regarding coverage of acupuncture. Traditional Medicare currently has an NCD for Acupuncture for Chronic Lower Back Pain (cLBP).[87] This NCD authorizes acupuncture for Medicare patients with chronic Lower Back Pain (cLBP) for up to 12 visits in 90 days under the following circumstance: lasting 12 weeks or longer; nonspecific, in that it has no identifiable systemic cause (that is, not associated with metastatic, inflammatory, infectious disease, etc.); not associated with surgery; and not associated with pregnancy. Here, an MA plan may require prior authorization, before authorizing treatment as a covered basic benefit, to verify the patient's pain is not the result of metastatic, inflammatory, infectious disease, as specified in the NCD. In this example, the plan is using the prior authorization to confirm a diagnosis specified in appropriate Medicare Part B coverage policy (in this case an NCD). Hence, prior authorization is used in this case to verify appropriate use of clinical standards and thus ensuring appropriate care, which is acceptable. Another example would be a beneficiary scheduled to undergo a non-emergency surgery. Here, an MA plan may use prior authorization before approving the surgery to review the beneficiary's medical history to verify that the surgery is medically necessary based on § 422.101(c)(1). In this example, the plan is using prior authorization to ensure that the surgery is clinically appropriate. (It is worth noting that if the surgery is an emergency or urgent surgery, or for stabilization purposes, then prior authorization would not be allowed).

CMS guidance (section 10.16 of Chapter 4 of the MMCM) currently states that if the plan approved the furnishing of a service through an advance determination of coverage, it may not deny coverage later on the basis of a lack of medical necessity. This means that when an enrollee or provider requests a pre-service determination and the plan approves this pre-service determination of coverage, the plan cannot later deny coverage or payment of this approval based on medical necessity. The only exception here would be medical necessity determinations for which the plan has the authority to reopen the decision for good cause or fraud or similar fault per the reopening provisions at § 422.616. This has been longstanding sub-regulatory guidance (section 10.16 of Chapter 4) that we are proposing to codify at § 422.138(c) to ensure the reliability of an MA organization's pre-service medical necessity determination. Therefore, we do not believe there is any additional impact. We solicit stakeholder input on the reasonableness of this assumption. We also solicit comment whether combining all of our proposals on prior authorization (here and in section III.E.4 of this proposed rule) in proposed new § 422.138 would make applying and understanding these requirements clearer for the public and MA organizations.

Finally, we also remind MA plans that section 1852(b) of the Act states that an MA plan may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the

[87] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=373.*

organization under this part, based on any health status–related factor described in section 2702(a)(1) of the Public Health Service Act. Additionally, per CMS regulations at § 422.100(f)(2), plan benefit designs may not discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. We consider prior authorization policies to be part of the plan benefit design, and therefore cannot be used to discriminate or direct enrollees away from certain types of services.

A complete estimation of impact on this provision cannot be given because we require detailed knowledge of proprietary plan information on the frequency and specific services for which prior authorization is done in each plan. We solicit comment from stakeholders on the impact and any additional information that would assist CMS in making an estimation.

4. Continuity of Care

In addition to the requirements of section 1852(d) of the Act, § 422.112(b) requires MA organizations that offer coordinated care plans to ensure continuity of care and integration of services through arrangements with contracted providers. Requirements in § 422.112(b)(1) through (b)(7) detail specific arrangements with contracted providers by which MA coordinated care plans are to ensure effective continuity and integration of health care services for their enrollees. This includes requiring MA coordinated care plans to have policies and procedures that provide enrollees with an ongoing source of primary care, programs for coordination of plan services with community and social services, and procedures to ensure that the MA coordinated care plan and its provider network have the information required for effective and continuous patient care and quality review.

a. Stakeholder Feedback

Stakeholders have communicated to CMS that MA coordinated care plans' prior authorization processes sometimes require enrollees to interrupt ongoing treatment. We also have received complaints that MA plans require repetitive prior approvals for needed services for enrollees that have a previously-approved plan of care or are receiving ongoing treatments for a chronic condition. When MA plans require repetitive prior approvals, enrollees may face delays in receiving medically necessary care or experience gaps in care delivery that threaten an enrollee's health.

b. Proposed Regulatory Changes

We believe the inclusion of additional continuity of care requirements at § 422.112 will help ensure coordinated care plans comply with and implement the statutory requirement (in section 1852 of the Act) that MA plans provide access to all medically necessary Medicare covered benefits. We propose to add a new paragraph (b)(8)(i) and (ii) at § 422.112 to set two new requirements for the use of prior authorization by MA coordinated care plans for covered Part A and B services (that is, basic benefits as defined in § 422.100(c)). Section 422.112(b) requires MA organizations offering coordinated care plans to ensure continuity of care and integration of services through arrangements with contracted providers that include the types of policies, procedures and systems that are specified in current paragraphs (b)(1) through (b)(7). First, we propose, at § 422.112(8)(i) that MA coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization for basic benefits. These prior authorization policies must reflect that all approved prior authorizations must be valid for the duration of the entire approved prescribed or ordered course of treatment or service. To illustrate this, if an MA coordinated care plan has approved a prescribed or ordered course of treatment or service for which the duration is 90 days, then the MA coordinated care plan's prior authorization approval must apply to the full 90 days, and the MA coordinated care plan may not subject this treatment or service to additional prior authorization requirements prior to the completion of the approved 90-day treatment or service. To further illustrate, if the MA coordinated care plan approves a prescribed or ordered course of treatment for a series of five sessions with a physical therapist, the MA coordinated care plan may not subject this active course of treatment or service to additional prior authorization requirements. We solicit comment on whether the prior authorization should be required to be valid for the duration of the prescribed order or ordered course of treatment provided that the criteria in proposed § 422.101(b) and (c) are met. Second, at § 422.112(b)(8)(ii)(A), we define ''course of treatment'' as a prescribed order or ordered course of treatment for a specific individual with a specific condition, as outlined and decided upon ahead of time, with the patient and provider. (A course of treatment may, but is not required to be part of a treatment plan). We also propose to define an ''active course of treatment'' at § 422.112(b)(8)(ii)(B) as a course of treatment in which a patient is actively seeing a provider and following the prescribed or ordered course of treatment as outlined by the provider for a particular medical condition.

Additionally, we propose at § 422.112(b)(8)(i)(B) that MA organizations offering coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider. This includes enrollees who are new to an MA coordinated care plan having either been enrolled in a different MA plan with the same or different parent organization, or an enrollee in Traditional Medicare and joining an MA coordinated care plan, and beneficiaries new to Medicare and enrolling in an MA coordinated care plan. The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

This means that for a minimum of 90 days, when an enrollee switches to a new MA coordinated care plan, any active course of treatment must not be subject to any prior authorization requirements. During the initial 90 days of an enrollee's enrollment with an MA coordinated care plan, the MA coordinated care plan cannot subject any active course of treatment (as defined at the proposed § 422.112(b)(8)(ii)(B)) to additional prior authorization requirements, even if the service is furnished by an out-of-network provider. We expect any active course of treatment to be documented in the enrollee's medical records so that the enrollee, provider, and MA plan can track an active course of treatment and avoid disputes over the scope of this proposed new requirement. We also intend that an active course of treatment can include scheduled procedures regardless whether there are specific visits or activities leading up to the procedure. To further illustrate, if an enrollee has a procedure or surgery planned for January 31st at the time of enrollment in a new MA coordinated care plan effective January 1, the new MA coordinated care plan must cover

this procedure without subjecting the procedure to prior authorization. The planned surgery is a part of an active course of treatment and thus cannot be subjected to prior authorization by the MA coordinated care plan in which the beneficiary has newly enrolled. In proposing to limit the way MA coordinated care plans use prior authorization for enrollees undergoing an active course of treatment, CMS seeks to ensure the availability and accessibility of basic benefits, which is consistent with section 1852 of the Act. CMS is proposing to use a 90 day transition policy here because it mirrors Part D transition requirements and using the same period will ensure consistency across the MA and Part D programs. In addition, use of one consistent transition period will likely make it easier for new enrollees to understand their transition coverage. We solicit public comment on alternative timeframes for transition periods of ongoing treatment, including the clinical and economic justification for alternative proposals.

CMS has authority to adopt standards to carry out the applicable MA provisions in Title XVIII of the Act and to add new contract terms that we find necessary, appropriate, and not inconsistent with the statute in sections 1856(b) and 1857(e) of the Act. In addition, section 1854(a)(5) and (6) of the Act provide that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. To the extent that these new minimum standards for MA organizations and how they cover benefits would not implement section 1852 of the Act, establish standards to carry out the MA program under section 1856(b) of the Act (which CMS does not concede as these are important protections to ensure that MA enrollees receive Medicare covered services), or be contract terms that we are authorized to adopt under section 1857(e)(1) of the Act, we believe that our negotiation authority in section 1854 of the Act permits creation of minimum coverage requirements. While the rules proposed here do not limit our negotiation authority (which is addressed in § 422.256), they provide minimum standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids, in addition to establishing important protections to ensure that enrollees have access to medically necessary items and services that are covered under Part A and Part B. We note that CMS has similar negotiation authority for the Part D program at section 1860D–11(d)(2) of the Act. CMS implemented a similar policy regarding coverage during a transition period using that authority and a similar explanation in the 2005 final rule (70 FR 4193). Our proposal is similar to Part D transitional requirements currently codified at § 423.120(b), which require Part D sponsors to provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on their Part D plan's formulary (including Part D drugs that are on a sponsor's formulary, but require prior authorization or step therapy under a plan's utilization management rules). Similar to Part D, as explained previously, we would establish a transition period for services provided as an active course of treatment to enrollees who switch from traditional Medicare to an MA plan and for when an enrollee switches from an MA a plan to another MA plan as described previously. Our experience with oversight and monitoring of the Part D program indicates that the transition policy has proved effective in ensuring continuity of care for Part D beneficiaries. Based on this experience, we believe it is appropriate to incorporate a similar beneficiary protection and coverage requirement in the MA program.

Coordinated care plans are already required to ensure continuity of care and integration of services through arrangements with contracted providers at 422.112(b). Therefore, some MA organizations may already be exercising discretion to waive prior authorization for enrollees undergoing an active course of treatment. However, CMS has received anecdotal feedback from stakeholders that care transitions can be difficult due to MA plan processes that require new coverage decisions when a patient transitions from one MA plan to another. However, we are not aware of the extent to which current MA plans are already ensuring continuity of care in this way nor do we have a strong basis upon which to quantify how often this type of transition occurs. Therefore, we are not quantifying the impact in this proposed rule and we solicit stakeholder input on both of these assumptions: that some MA plans are providing continuity of care as defined in the proposed § 422.112(b)(8) today and the lack of available data by which to quantify it.

5. Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee (§ 422.137)

We are proposing procedural improvements to ensure that utilization management policies are reviewed on a timely basis and have the benefit of provider input. Any authority for MA organizations to use utilization management policies with regard to basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards for to carry out the MA provisions. In light of the feedback we have received and our concern that enrollees may be facing unreasonable barriers to needed care, we propose to require MA organizations to establish a Utilization Management (UM) committee to operate similar to a Pharmacy and Therapeutics, or P&T, committee. We propose to add requirements pertaining to this UM committee in a new regulation at § 422.137.

a. Review and Approval of UM Policies

At § 422.137(a), we propose that an MA organization that uses utilization management (UM) policies, such as prior authorization, must establish a UM committee that is led by an MA plan's medical director (described in § 422.562(a)(4)). Section 422.562(a)(4) requires every MA organization to employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity and establishes that the medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We are also proposing, at § 422.137(b), that an MA plan may not use any UM policies for basic or supplemental benefits on or after January 1, 2024, unless those policies and procedures have been reviewed and approved by the UM committee. This proposal would ensure that plan policies and procedures meet the standards set forth in this proposed rule beginning with the contract year after the finalization of this proposed rule. We anticipate that there will be sufficient time between our issuance of a final rule and January 1, 2024, for each MA organization to engage in the necessary administrative activity to establish the UM committee and have its existing UM policies reviewed and, if they meet the standards in this proposed regulation, approved for use.

We propose the committee responsibilities at § 422.137(d). The responsibilities would include that the

UM committee, at least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. We propose at § 422.137(d)(1)(i) through (iii) that such review must consider—

- The services to which the utilization management applies;
- Coverage decisions and guidelines for original Medicare, including NCDs, LCDs, and laws; and
- Relevant current clinical guidelines.We propose at § 422.137(d)(2)(i) though (iv) the committee approve only utilization management policies and procedures that:
- Use or impose coverage criteria that comply with the requirements and standards at § 422.101(b);
- Comply with requirements and standards at § 422.138(a)–(c);
- Comply with requirements and standards at § 422.202(b)(1); and
- Apply and rely on medical necessity criteria that comply with § 422.101(c)(1).

Currently, § 422.202(b) requires MA organizations to establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures; that formal mechanism for consultation must ensure that certain standards are met. Specifically, § 422.202(b)(1)(i) through (iv) require that MA plan practice guidelines and UM guidelines must: (i) be based on reasonable medical evidence or a consensus of health care professionals in the particular field; (ii) consider the needs of the enrolled population; (iii) be developed in consultation with contracting physicians; and (iv) be reviewed and updated periodically. We are proposing to modify § 422.202(b)(1)(i) to align it with our standard for creating internal coverage criteria. We therefore propose to replace the requirement that practice and UM guidelines be based on reasonable medical evidence or a consensus of health care professionals in the particular filed with a requirement that UM guidelines be based on current widely used treatment guidelines or clinical literature. This is consistent with the proposed coverage criteria requirements at § 422.101(b)(6), which are discussed in detail in section III.E.2. of this proposed rule.

We solicit comment on whether we should also require the UM committee to ensure that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure, as required by § 422.202(b)(2), that MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees; and whether the UM committee should have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies. We also propose at § 422.137(d)(3) that the committee must revise UM policies and procedures as necessary, and at least annually, to comply with the standards in the regulation, including removing requirements for UM for services and items that no longer warrant UM so that UM policies and procedures remain in compliance with current clinical guidelines. Mandating annual review of utilization management policies using these standards will help ensure that medically necessary services are accessible to all enrollees. Because prior authorization and referral or gatekeeper policies are included in UM policies and procedures, these proposed requirements would apply as well to those polices used by MA organizations. CMS expects MA organizations to update their UM policies after the UM committee approves or revises them. We solicit comment as well on the extent to which the proposed regulation text sufficiently and clearly establishes the standards and requirements discussed here.

We are considering whether the duties of this UM Committee should be expanded to include all internal coverage policies of an MA plan (or at least of all coordinated care plans). Whether a policy is explicitly called ''utilization management'' or a ''coverage criteria,'' the policy can limit enrollee access to plan-covered services. As this proposed rule as a whole makes clear, ensuring that enrollees have access to and are furnished covered benefits is a priority. We solicit comment on whether to require the UM Committee to review all internal coverage criteria used by the MA plan.

b. Utilization Management Committee Membership

At § 422.137(c)(1) through (4), we propose that the UM committee must include a majority of members who are practicing physicians; include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan; include at least one practicing physician who is an expert regarding care of elderly or disabled individuals; and include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies. These composition requirements are in addition to the proposal that the medical director, required for each MA plan under § 422.562(a)(4), lead the UM committee.

We solicit comment on recommendations for other types of providers, practitioners, or other health care professionals that should also be included on the UM committee and whether additional standards for composition of the UM committee are necessary with regard to expertise, freedom of conflicts of interest, or representation by an enrollee representative. We have received feedback from the provider community that UM policies for specific services or items are often not reviewed by providers with the expertise appropriate for the service. Therefore, we also solicit comment on whether we should include a requirement, that when the proposed UM committee reviews UM policies applicable to an item or service, that the review must be conducted with the participation of at least one UM committee member who has expertise in the use or medical need for that specific item or service.

c. Documentation of Determination Process

We propose at § 422.137(d)(4) that the UM committee must clearly articulate and document processes to determine that the requirements under paragraphs (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. Finally, we propose at § 422.137(d)(5) that the UM committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. The documentation should provide CMS with an understanding of the UM committee's rationale for their decision, and may include, but is not limited to, information such as meeting minutes outlining issues discussed and any relevant supporting documentation.

d. Interchangeable Use of the P&T and Utilization Management Committees

We believe it is appropriate that this proposal for the establishment of an MA plan UM committee largely mirror, with certain exceptions, the requirements in

§ 422.136 that MA organizations have a pharmacy and therapeutic committee that reviews and approves step therapy programs for Part B drugs and the requirements regarding membership, scope, and responsibilities of that P&T committee. We believe that similar requirements, which were modeled after the longstanding Part D P&T committee requirements at § 423.120(b), are generally adequate for the purposes of the UM committee. Overall, this proposal is designed to require review and approval of utilization management policies, including utilization management policies that use or impose coverage criteria, to ensure that these policies and procedures are medically appropriate, consistent with Medicare coverage rules, and do not negatively impact access to medically necessary services.

To meet the existing requirements at § 422.136(b), MA–PDs are permitted to utilize an existing P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter. Thus, we anticipate that some of the requirements proposed for the UM committee may overlap or duplicate existing P&T committee requirements in connection with coverage of and utilization management policies for Part B drugs. Therefore, we solicit comment on whether an MA plan should be permitted to utilize the proposed UM committee at § 422.137 to also meet the existing P&T committee requirements of § 422.136(b), provided that elements and requirements of all applicable regulations governing the committees and their functions (that is, §§ 422.136, proposed 422.137, and 423.120) are met. To the extent that LCD policies and localized or regional professional standards of practice are used by the proposed UM committee in performing its duties, it may not be advisable to permit use of one UM committee to serve multiple functions for diverse service areas. We also solicit comment on whether to explicitly permit an MA organization, or the parent organization of one or more MA organizations, to use one UM committee to serve multiple MA plans, including whether that should be limited to MA plans that are offered under the same contract.

6. Additional Areas for Consideration and Comment

a. Termination of Services in Post-Acute Care

We have received complaints about potential quality of care issues regarding early termination of services in post-acute care settings by MA organizations. The complaints allege that MA organizations are increasingly terminating beneficiaries' coverage of post-acute care before the beneficiaries are healthy enough to return home. It is further alleged that, in some situations, even after a beneficiary has successfully appealed to the Quality Improvement Organization (QIO) and received a favorable decision to reauthorize coverage of services delivered by providers of services described in §§ 422.624 and 422.626, the MA organization sends another notice of termination of services a day or two after the coverage was reinstated. As described in section III.E.2. of this proposed rule, we are proposing to revoke the current policy, outlined in the June 2000 final rule, that when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, an MA plan could choose how the covered services will be provided. Under the proposal at § 422.101(c)(1)(i), when care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may only deny coverage of the services or setting on the basis of the ordered services failing to meet the criteria outlined in § 422.101(c)(1)(i) While CMS believes this may address some of the issues regarding early termination of services, we are soliciting feedback from stakeholders that have information related to this situation, and investigating internally, in order to get a more thorough understanding on the issue.

The rules at 42 § 422.624 define what constitutes a termination of services from home health agencies, SNFs, and comprehensive outpatient rehabilitation facilities and how enrollees must be notified of upcoming terminations of services. We solicit comment on potential changes we could make to existing rules, including § 422.624, or in adopting new rules to better manage incentives between MA organizations and post-acute care providers to deliver the best possible care for Medicare beneficiaries. Some topics for comment include:

- How MA organizations preauthorize treatment in discrete increments and the extent to which our proposals (at proposed §§ 422.101(b) and (c) and 422.112(b)(8)) may address or limit these practices;
- Whether enrollees should have additional time to file appeals or be able to file late appeals to the QIO regarding terminations of services;
- Whether enrollees should receive information from the MA plan regarding the basis for termination of services (for example, the clinical rationale for termination of services) as part of the termination notice and without the enrollee having to request an appeal to the QIO (see § 422.626(e)(1) and (2));
- When coverage is reinstated based on a QIO decision, whether the enrollee should have more than the 2 day period from the date of a new termination of services notice before coverage can be terminated again by the MA organization, taking into account any medical necessity determinations made by the QIO.

We thank commenters in advance for carefully considering and providing information on this important issue.

b. Gold Carding

In the 2020 proposed rule titled ''Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications,'' which appeared in the **Federal Register** on December 18, 2020 (85 FR 82586), (hereinafter the December 2020 proposed rule), CMS requested comments on ''gold-carding,'' MA plan programs that relax or reduce prior authorization requirements for contracted providers that have demonstrated a consistent pattern of compliance with plan policies and procedures. At 85 FR 82619, CMS noted that some MA plans relieve certain contracted providers from prior authorizations requirements based on consistent adherence to plan requirements, appropriate utilization of items or services, and other evidence-driven criteria that the MA plan deems relevant. In the December 2020 proposed rule, CMS also discussed its own experience and success with a similar approach in the Medicare FFS Review Choice Demonstration for Home Health Services.[88] It is appropriate to reiterate in this rule that we believe the use of gold-carding programs could help alleviate the burden associated with prior authorization and that such

[88] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Choice-Demonstration/Review-Choice-Demonstration-for-Home-Health-Services.html.*

programs could facilitate more efficient and timely delivery of health care services to enrollees. We encourage MA plans to adopt gold-carding programs that would allow providers to be exempt from prior authorization and provide more streamlined medical necessity review processes for providers who have demonstrated compliance with plan requirements.

c. Address Vulnerabilities That Can Lead to Manual Review Errors and System Errors

Finally, the April 2022 OIG report indicated that some denials were the result of MA plan errors. This included both human and system related errors. For example, the OIG found situations where a request was denied because the MA plan reviewer misidentified important information in a request. They also found situations where a request was denied because provider coverage details were incorrectly configurated in the MA plan's system. As a result of these findings, the OIG recommends that CMS should direct MA organizations to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors. We concurred with this recommendation, and are directing MA plans to review PA procedures, protocols, and systems to identify and address vulnerabilities that can lead to errors. Currently, § 422.503(b)(4) requires all MA organizations to have administrative and management arrangements that include an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse; MA organizations are required to include in this compliance program the establishment and implementation of an effective system for routine monitoring and identification of compliance risks. Failure to furnish medically necessary covered services in a timely manner implicates compliance with §§ 422.100, 422.101 and 422.112 at a minimum, and we believe that the OIG's April 2022 report has sufficiently identified this area as a compliance risk that MA organizations must address in accordance with § 422.503(b)(4)(vi)(F) and (G).

We solicit comment on whether and how existing requirements at § 422.503(b)(4)(vi) may be adjusted to better account for these medical review and system errors. In addition, we solicit comment whether proposed § 422.137 should include a provision for the UM committee to develop, implement and oversee activities by MA organizations related to utilization policies and procedures.

F. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS is soliciting comment on a potential revision to the regulation governing MA Reward and Incentive (R&I) programs. CMS first authorized MA organizations to offer R&I programs in a regulation (§ 422.134) finalized in 2014 (79 FR 29956, published May 23, 2014) and subsequently updated that regulation in a January 2021 final rule titled ''Medicare and Medicaid Programs; Contract Year 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'' (85 FR 5864, January 21, 2021).

CMS's intent in adopting § 422.134 to authorize MA R&I programs to be offered by MA organizations is to incentivize healthy behaviors among enrollees. Under § 422.134, MA plans have the option to uniformly offer enrollees rewards in exchange for participating in health related activities which either promote improved health, prevent injury and illness, or promote efficient use of health care resources. Our experience has shown that these programs have been successful to date.

In adopting the regulation governing MA R&I programs, we relied on our authority under sections 1856(b)(1) and 1857(e)(1) of the Act. In addition, several of the provisions of the regulation, such as compliance with relevant fraud and abuse laws including the Federal anti-kickback statute and compliance with MA program anti-discrimination provisions, are consistent with laws governing the Medicare program and the MA program as whole.

Sections 1851(h)(4) and 1854(d)(1) of the Act prohibit an MA organization from giving enrollees cash or monetary rebates as an inducement for enrollment or otherwise. Based on this statutory prohibition of cash or cash equivalents, CMS prohibits a reward item consisting of cash or cash equivalents at 42 CFR 422.134(d)(2)(i). In the proposed rule titled ''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'' which appeared in the February 18, 2020 **Federal Register** (85 FR 9002), we explained that we were proposing at that time to adopt the Office of Inspector General (OIG)'s definition of cash equivalents (81 FR 88393), which defined ''cash equivalents'' as items convertible to cash (such as a check) or items that can be used like cash (such as a general purpose debit card) but not including a gift card that can be redeemed only at certain store chains or for a certain purpose, like a gasoline card. CMS finalized § 422.134(d)(3)(ii) in a January 2021 final rule with a provision that it is permissible for an MA organization's R&I program to offer a gift card ''that can be redeemed only at specific retailers or retail chains or for a specific category of items or services.''

However, we have been prompted by several considerations suggesting that CMS may need to further revise and clarify the definition of ''cash equivalent'' in the framework of MA R&I programs. First, in a recent rule (85 FR 77684, December 2, 2020), OIG explained that cash equivalents include ''gift cards offered by large retailers or online vendors that sell a wide variety of items (for example, big-box stores) . . .''. Additionally, the January 2021 CMS final rule also finalized authority for a separate R&I program in connection with a Part D real time benefit tool requirement at § 423.128(d)(4) and (5). In the preamble of that regulation, CMS was clear that a gift card would be considered a cash equivalent when it could be used for large retailers like Amazon.

In addition, another CMS rule (entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' published on December 31, 2018 (83 FR 67816, 67980)) characterizes Amazon gift cards as cash equivalents because they could be used for a variety of diverse purchases, which makes the gift card usable like cash (86 FR 5954).

Finally, in our January 2021 final rule adopting § 422.134, we did not specifically address gift cards from big-box stores nor did we discuss them in relation to the prohibition on cash equivalents in § 422.134(d)(2)(i). CMS has since received inquiries from various stakeholders requesting a definition of 'big-box store' in the context of MA R&I program gift cards.

Because of these considerations and to clarify the scope of prohibited cash equivalents for the purposes of MA Reward & Incentive programs, we are

soliciting comment on whether CMS should further clarify the definition of ''cash equivalent'' as that term is used in § 422.134. CMS is particularly interested in stakeholder feedback on whether CMS should revise our MA R&I program regulation to include parameters for permissible gift cards being offered as MA reward items. We are interested in learning how MA plans interpret and implement our current guidance and whether stakeholders believe that more specific guidance on permissible gift card reward items is necessary. We welcome feedback on all aspects of this issue.

G. Section 1876 Cost Contract Plans and Cost-Sharing for the COVID–19 Vaccine and its Administration (§ 417.454)

Section 3713 of The Coronavirus Aid, Relief, and Economic Security (CARES) Act (2020) (Pub. L. 116–136) requires coverage of the COVID–19 vaccine and its administration at zero cost-sharing for enrollees of Traditional Medicare and Medicare Advantage. The CARES Act revised section 1861(s)(10)(A) of the Act to include among services provided at zero cost-sharing in the Medicare FFS program, the COVID–19 vaccine and its administration. As amended by section 3713 of the CARES Act, section 1852(a)(1)(B)(iv)(VI) of the Act prohibits MA plans from using cost-sharing that exceeds the cost-sharing imposed under traditional Medicare for a COVID–19 vaccine and its administration when the MA plan covers this Traditional Medicare benefit.

Cost plans are coordinated care plans and share many of the same features as Medicare Advantage plans but have a separate statutory authority (section 1876 of the Act) and are paid on a reasonable cost basis, In addition, unlike with MA plans, enrollees in cost plans may receive services from original Medicare in addition to services from the cost plan's network; when they receive benefits from healthcare providers that are not contracted with the cost plan, cost plan enrollees are covered by original Medicare, with the same cost sharing and coverage as the Traditional Medicare program. The CARES Act did not include the zero cost-sharing provision for section 1876 cost contract plans (cost plans), so using its authority under section 1876(i)(3)(D) of the Act, which authorizes CMS to impose ''other terms and conditions not inconsistent with [section 1876]'' that are deemed ''necessary and appropriate,'' CMS established a requirement for cost plans to use cost sharing that does not exceed the cost sharing in Traditional Medicare for a COVID–19 vaccine and its administration in an interim final rule, titled Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, which appeared in the **Federal Register** on November 6, 2020.[89] Because of the cost sharing used in Traditional Medicare per sections 1833(a)(1)(B) and 1861(s)(10)(A) of the Act, this is effectively a requirement to cover this benefit with zero cost sharing. In a newly adopted § 417.454(e)(4), we specified the timeline for coverage of a COVID–19 vaccine and its administration with zero cost-sharing for cost plans coverage of cost-sharing for cost plans that may not exceed cost sharing under Traditional Medicare as the ''duration of the PHE for the COVID–19 pandemic, specifically the end of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Act, which is the PHE declared by the Secretary on January 31, 2020 and any renewals thereof.'' However, the CARES Act did not specify an end date for the zero cost-sharing requirement for MA plans and we believe that it is appropriate that enrollees in a section 1876 cost plan have the cost sharing protection for a COVID vaccine and its administration enrollees in the Medicare FFS program and in MA plans have when these cost plan enrollees get this benefit from healthcare providers that are in-network with the cost plan. Therefore, we are proposing to replace the provision adopted at § 417.454(e)(4) in the November 2020 interim final rule with a new requirement that section 1876 cost plans cover without cost-sharing the COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act. This proposal is based on authority in section 1876(i)(3)(D) of the Act to add requirements for cost plans.

CMS believes that it is necessary and appropriate to ensure that cost plan enrollees, like other Medicare beneficiaries, are provided access to the COVID–19 vaccine and its administration without cost-sharing in-network. Requiring cost plans to comply with the same cost-sharing protections available to Medicare beneficiaries in traditional Medicare and those enrolled in MA plans would ensure equitable access to care and that cost is not a barrier for beneficiaries to receive the COVID–19 vaccine. CMS has extended to cost plans other statutory requirements related to cost-sharing via regulation for those services that the Secretary determines require a level of predictability and transparency for beneficiaries. For example, in a final rule which appeared in the **Federal Register** on April 15, 2011, CMS, using its authority under section 1876(i)(3)(D) of the Act, extended to cost plans the statutory requirements specifying that in-network cost-sharing for MA enrollees could not be higher than cost-sharing for traditional Medicare enrollees for chemotherapy administration services, renal dialysis services, and skilled nursing care in those cost sharing protections are § 417.454(e)(1) through (e)(3). We welcome comment on this proposal.

H. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional With Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629)

Based on general feedback CMS has received from provider associations regarding the use of prior authorization (PA) by MA organizations and the submission and review of clinical documentation to support a request for coverage of a service subject to PA, we are proposing to modify the requirement in §§ 422.566(d) and 422.629(k)(3) with respect to the expertise of the physician or other appropriate health care professional who must review an organization determination if the MA organization or applicable integrated plan (AIP), defined at § 422.561, expects to issue an adverse decision based on the initial review of the request. Pursuant to our authority under section 1856(b) of the Act to adopt standards to carry out the Part C program and in order to implement section 1852(g) of the Act regarding coverage decisions and appeals, CMS established procedures and minimum standards for MA plans to make organization determinations and reconsiderations regarding benefits. In addition, CMS adopted unified grievance and appeal procedures using authority in section 1859(f)(8)(B) of the Act to establish such unified procedures for D–SNPs; we limited the unified procedures to AIPs, a subset of D–SNPs, when adopting those procedures. These requirements are codified in our regulations at 42 CFR part 422, subpart M. In addition, because cost plans must comply with the beneficiary appeals and grievance rights, procedures, and requirements at Part 422, subpart M, per §§ 417.600(b) and 417.840, these proposals apply to cost plan and healthcare prepayment plan appeals as well.

[89] See interim final rule with request for comments titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' CMS 9912 IFC, 85 FR 71142.

Specifically, section 1852(g)(1)(A) of the Act requires that a MA organization have a procedure for making determinations regarding whether an enrollee is entitled to receive a health service and the amount (if any) the individual is required to pay for such service and, further, that such procedures provide that determinations be made on a timely basis, subject to section 1852(g)(3) of the Act (which provides for expedited determinations and reconsiderations as part of the MA plan's appeal process). Section 1852(g)(2)(B) of the Act requires plan reconsiderations related to coverage denials that are based on medical necessity determinations to be made by a physician with appropriate expertise in the applicable field of medicine, and that the physician reviewer be different from the physician or other health care professional involved in the initial determination. While section 1852(g)(1)(A) of the Act does not specify who must conduct the initial medical necessity determinations, we interpret the reference in section 1852(g)(2)(B) of the Act to the physician involved in the initial determination to mean that MA plans must have appropriate health care professionals review initial determinations involving issues of medical necessity. This is an established interpretation of the statute and is reflected in existing regulations related to review of organization determinations. Specifically, the current regulation at § 422.566(d) states that if the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. The current regulation at § 422.629(k)(3) also applies the same requirement to AIPs with the additional requirement that the health care professional also have knowledge of Medicaid coverage criteria.

We are proposing to revise §§ 422.566(d) and 422.629(k)(3) to add to that existing requirement that the physician or other appropriate health care professional who conducts the review must have expertise in the field of medicine that is appropriate for the item or service being requested before the MA organization or AIP issues an adverse organization determination decision. In other words, we are proposing that the existing regulation text with the more general requirement that the physician or other appropriate health care professional have sufficient medical and other expertise be replaced by a requirement linking the requisite expertise of the reviewer to the specific service that is the subject of the organization determination request. Under this proposal, the physician or other appropriate health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. This is the same standard set forth at § 422.590(h)(2) related to the appropriate expertise applicable to physician review of reconsiderations. The rule at § 422.590(h)(2) interprets and implements the requirement in section 1852(g)(2)(B) of the Act that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity be made only by ''a physician with appropriate expertise in the field of medicine which necessitates treatment'' to mean a physician with an expertise in the field of medicine that is appropriate for the covered services at issue. The standard of requiring a reviewing physician's expertise to be appropriate for the specific service at issue is long-standing policy with respect to plan reconsiderations and we believe it is appropriate as well as practical to adopt this standard for the review of organization determinations by physicians and other appropriate health professionals in §§ 422.566(d) and 422.629(k)(3). Specifically, this proposed approach would strengthen clinical review in the organization determination process, while continuing to afford plans maximum flexibility in leveraging reviewer resources.

If this proposal is finalized, we expect MA organizations, including AIPs, to apply the standard of ''expertise appropriate for the specific service at issue'' at the organization determination level in the same manner as plans have applied this standard at the reconsideration level. As explained in the final rule establishing the Medicare+Choice program (65 FR 40170, 40288), published June 29, 2000, which later became the Medicare Advantage program, and in established sub-regulatory guidance, if the physician is not of the same specialty or subspecialty as the treating physician, the physician must have the appropriate level of training and expertise to evaluate the necessity of the requested drug, item, or service. This does not require the physician involved to be of the exact same specialty or sub-specialty as the treating physician. As an example, where there are few practitioners in a highly specialized field of medicine, a plan may not be able to retain the services of a physician of the same specialty or sub-specialty to review the organization determination. Plans will have discretion to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition. For example, if an enrollee is referred by a primary care physician to a thyroid surgeon for a thyroid nodule removal, the health professional evaluating the request prior to the plan issuing a denial should be a doctor with thyroid expertise, but does not necessarily need to be a surgeon. As another example, if a plan intends to deny a request for a home nebulizer, the organization determination request should be reviewed by a health professional with respiratory expertise, such as a respiratory therapist.

If finalized, we believe this proposal will enhance the existing requirement for who is permitted to review organization determinations that deny coverage in whole or in part, while retaining plan flexibility and operational efficiency in selecting appropriate reviewers. We reiterate that this requirement applies when the MA organization or AIP expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request and does not limit the scope of reviewers where the plan approves coverage or determines that an item or service is medically necessary. From the perspective of enrollees and providers who request coverage on an enrollee's behalf or submit clinical documentation to support a coverage request, we believe this review standard will increase the likelihood of a thorough clinical review. Requiring expertise related to the requested service, as we are proposing, will enhance the overall decision-making process and the quality of the review conducted at the organization determination level, particularly when a prior authorization or other utilization management requirement on the requested item or service necessitates review of specific clinical

documentation to support coverage. Further, we believe this proposal may reduce coverage denials at the organization determination level that could then be subject to the administrative appeals process. As a whole, we believe that this proposal strikes the appropriate balance between the proper clinical review of organization determinations and minimizing overall burden in the administration of the Part C benefit for MA plans and AIPs.

While the proposed requirement that the physician or other appropriate health care professional have expertise in the field appropriate to the requested service may result in AIPs and other MA organizations reallocating staff resources in certain cases to ensure that someone with appropriate expertise is reviewing the request, we believe that the burden will be negligible and that this proposal will not require changes to AIPs and other MA organizations overall staffing. While performing a review of an organization determination request involves review of clinical documentation, this proposal would not impose any new information collection or recordkeeping requirements on AIPs or other MA organizations.

In the course of this rulemaking, we noticed the need for a technical correction in § 422.590(b)(1), which cross references the effectuation requirements in § 422.618. Section 422.590(b)(1) erroneously cites to § 422.618(a)(1), but it should cite to the effectuation requirements at § 422.618(a)(2) related to favorable decisions on payment requests. Thus, we propose to make the technical correction in this rule.

We welcome comments on this proposal and the technical correction.

I. Effect of Change of Ownership Without Novation Agreement (§§ 422.550 and 423.551)

In accordance with standards under sections 1857 and 1860 of the Act, each Medicare Advantage (MA) organization and Part D sponsor is required to have a contract with CMS in order to offer an MA or prescription drug plan. Further, section 1857(e)(1) and 1860D–12(b)(3)(D) of the Act authorizes additional contract terms consistent with the statute and which the Secretary finds are necessary and appropriate. Pursuant to this authority and at the outset of the Part C and Part D programs, we implemented contracting regulations at §§ 422.550 and 423.551, respectively, which provide for the novation of an MA or Part D contract in the event of a change of ownership involving an MA organization or Part D sponsor (63 FR 35106 and 70 FR 4561).

Our current regulations at §§ 422.550 and 423.551, as well as our MA guidance under ''Chapter 12 of the Medicare Managed Care Manual—Effect of Change of Ownership'' [90] require that when a change of ownership occurs, as defined in the regulation, advance notice must be provided to CMS and the parties to the transaction must enter into a written novation agreement that meets CMS' requirements. If a change of ownership occurs and a novation agreement is not completed and the entities fail to provide notification to CMS, the regulations at §§ 422.550(d) and 423.551(e) indicate that the existing contract is invalid. Furthermore, §§ 422.550(d) and 423.551(e) provide that if the contract is not transferred to the new owner through the novation process, the new owner must enter into a new contract with CMS after submission of an MA or Part D application, if needed.

The current regulation does not fully address what happens when the contract becomes ''invalid'' due to a change of ownership without a novation agreement and/or notice to CMS, or in other words, what happens to the existing CMS contract that was held by an entity that was sold. This presents an issue because CMS would still recognize the original entity as the owner, even if the contract is now held by a different entity. Therefore, we are proposing to revise §§ 422.550(d)(1) and 423.551(e)(1) to make it clear that in this case, the affected contract may be unilaterally terminated by CMS in accordance with §§ 422.510(a)(4)(ix) and 423.509(a)(4)(ix), which establishes that failure to comply with the regulatory requirements contained in part 422 (or part 423 if applicable) is a basis for CMS to terminate an MA or Part D contract. In addition, we are strengthening our enforcement authority regarding this process, with the proposed amendments to §§ 422.550(d) and 423.551(e). Pursuant to our authority under sections 1857 and 1860 of the Act, we propose to amend the regulations at §§ 422.550(d) and 423.551(e) to outline the process CMS will follow, including imposing applicable sanctions before terminating a contract that has a change in ownership without a novation agreement, in accordance with CMS requirements.

In the interest of protecting and effectively managing the MA and Part D programs, CMS, through the application process, must ensure that MAOs through their respective legal entities are deemed eligible to contract with CMS. Thus, any change in ownership from one legal entity to another requires CMS to determine whether the new organization continues to meet the regulatory requirements for operating a contract under the MA and Part D programs. If this does not happen and a change in ownership from one legal entity to another occurs without CMS approval, it compromises our ability to ensure the integrity of the MA and Part D programs and further puts at risk our ability to monitor a contract's activity under the new legal entity, thereby putting enrollees at risk. We propose to provide an opportunity for organizations to demonstrate that the legal entity that is assuming ownership by way of novation is able to meet the requirements set forth by our regulations.

We propose to impose intermediate enrollment and marketing sanctions, as outlined in § 422.750(a)(1) and (a)(3) and § 423.750(a)(1) and (a)(3) on the affected contract, that will remain in place until CMS approves the Change of Ownership, (including execution of an approved novation agreement) or the contract is terminated. This may be completed in the following ways:

- If the new owner does not participate in the same service area as the affected contract, at the next available opportunity, it must apply for and be conditionally approved for participation in the MA or Part D program and within 30 days of the conditional approval (if not sooner) submit the documentation required under §§ 422.550(c) or 423.551(d) for review and approval by CMS (note that organizations may submit both the application and the documentation for the change of ownership concurrently); or
- If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions, submit the documentation required under §§ 422.550(c) or 423.551(d) for review and approval by CMS.

If the new owner is not operating in the same service area and fails to apply at the next opportunity, the existing contract will be subject to termination in accordance with §§ 422.510(a)(4)(ix) or 423.509(a)(4)(x). Or if the new owner is operating in the same service area and fails to submit the required documentation within 30 days of imposition of intermediate sanctions, the existing contract will be subject to

[90] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c12.pdf.*

termination in accordance with §§ 422.510(a)(4)(ix) or 423.509(a)(4)(x).

This action would be subject to the past performance rules applicable under §§ 422.502(b)(1) or 423.503(b)(1).

We solicit comments on these proposals.

J. Civil Money Penalty Methodology (§§ 422.760 and 423.760)

Sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act provide CMS with the ability to impose Civil Money Penalties (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. 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 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 [91] for each affected enrollee or per determination, however CMS does not necessarily apply the maximum penalty amount authorized by the regulation in all instances because the penalty amounts under the current CMP calculation methodology are generally 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.[92]

On January 19, 2021, CMS published a final rule in the **Federal Register** titled ''Medicare and Medicaid Programs; Contract Year 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'' (86 FR 5864). In that final rule, CMS finalized a policy, effective beginning in CY 2022, to update the minimum CMP penalty amounts no more often than every three years. Under this policy, CMS updates the CMP penalty amounts by including the increases that would have applied if CMS had multiplied the minimum penalty amounts by the cost-of-living multiplier released by the Office of Management and Budget (OMB) [93] each year during the preceding three-year period. CMS also tracks the yearly accrual of the penalty amounts and announces them on an annual basis.

The intent of the minimum penalty increase policy was to establish the CMP calculation methodology document in regulation to ensure consistency and transparency with CMP penalty amounts. Although parts of the regulations at §§ 422.760(b)(3) and 423.760(b)(3) have set standards for CMP penalties, in hindsight, CMS believes that other parts of the regulations unnecessarily complicated CMS's approach to calculating CMPs, which has the effect of limiting CMS's ability to protect beneficiaries when CMS determines that an organization's non-compliance warrants a CMP amount that is higher than would be normally be applied under the CMP methodology. In addition, although CMS always has had the authority to impose up to the maximum authorized under sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act, parts of the minimum penalty increase policy may have inadvertently given the impression that CMS was limiting its ability to take up to the maximum amount permitted in statute and regulation. This was not the intent of the rule. For example, there may be instances where an organization's non-compliance has so substantially adversely impacted one or more enrollees, that CMS would determine it necessary to impose the maximum CMP amount, or an amount higher than the amount set forth in the CMP methodology guidance to adequately address the non-compliance. In order to clarify its ability to adequately protect beneficiaries and encourage compliance, CMS proposes to modify its rules pertaining to minimum penalty amounts.

Specifically, CMS proposes to remove §§ 422.760(b)(3)(i)(E) and 423.760(b)(3)(i)(E), respectively, which is the cost-of-living multiplier. CMS also proposes to remove §§ 422.760(b)(3)(ii)(A)–(C) and 423.760(b)(3)(ii)(A)–(C), which describes how CMS calculates and applies the minimum penalty amount increase. Lastly, CMS proposes to revise and add new provisions §§ 422.760(b)(3) and 423.760(b)(3), which explains that CMS will set standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties in accordance with paragraphs (b)(1) and (b)(2) of this paragraph on an annual basis, and restates that CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

If finalized, CMS would continue to follow our existing CMP methodology and would only impose up to the maximum CMP amount in instances where we determine non-compliance warrants a higher penalty. This update would also be incorporated in forthcoming revised CMP calculation methodology guidance.

We solicit comment on these proposals.

K. Call Center Interpreter Standards (§§ 422.111(h)(1)(iii)(A) and 423.128(d)(1)(iii)(A))

CMS is proposing to amend §§ 422.111(h)(1)(iii)(A) and 423.128(d)(1)(iii)(A) to establish standards for interpreter services utilized by MA organizations and Part D sponsors in connection with their toll-free customer call centers. CMS relies on the Secretary's authority at sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act to adopt additional contract terms and conditions as the Secretary may find necessary and appropriate, and not inconsistent with the statute, to adopt these additional requirements for MA

[91] 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 §§ 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 of the Act solely references per determination calculations for Medicare Cost Plans. Therefore, the maximum monetary penalty amount applicable is the same as § 422.760(b)(1).

[92] CMS Civil Money Penalty Calculation Methodology, Revised. June 21, 2019. *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019CMPMethodology06212019.pdf.*

[93] 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.

organizations and Part D sponsors. CMS also relies on the authority in sections 1852(c)(1) and 1860D–4(a)(1)(B) of the Act, under which MA organizations and Part D sponsors must disclose detailed information about plans, to establish call center requirements. These proposed interpreter standards will ensure adequate and appropriate access to information for non-English speaking and Limited English Proficiency (LEP) Medicare beneficiaries, such that the information disclosure requirements for MA organizations and Part D sponsors are met and enrollment in MA and Part D plans is accessible for these groups.

Specifically, we propose to require MA organizations and Part D sponsors to use interpreters that adhere to generally accepted interpreter ethics principles, including confidentiality; demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

CMS has consistently stated that MA organizations and Part D sponsors should use appropriate interpreters to ensure that non-English speaking and LEP beneficiaries have access to assistance. On January 2, 2008, CMS released an HPMS memo, ''Best Practices for Addressing the Needs of Non-English Speaking and Limited English Proficient (LEP) Beneficiaries,'' which suggested that Part D sponsors and MA organizations review additional HHS guidance on developing an effective plan for language assistance for LEP beneficiaries. This guidance, titled ''Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,'' appeared in the **Federal Register** on August 8, 2003 (68 FR 47311) and provided the following criteria to determine the competency of interpreters: demonstrate proficiency in and ability to communicate information accurately in both English and in the other language; have knowledge in both languages of any specialized terms or concepts peculiar to the recipient's program or activity and of any particularized vocabulary and phraseology used by the LEP person; and understand and follow confidentiality and impartiality rules. Additionally, since 2010, CMS has annually encouraged MA organizations and Part D sponsors to review and use the Office of Minority Health's (OMH) National Standards on Culturally and Linguistically Appropriate Services (CLAS), originally published in 2001 and most recently updated in 2018.[94] The CLAS standards include a requirement to provide competent language assistance services. Most recently, in our December 16, 2021 HPMS memo titled ''2022 Part C and Part D Call Center Monitoring—Timeliness and Accuracy & Accessibility Studies,'' we recommended that MA organizations and Part D sponsors use interpreters that adhere to generally accepted interpreter ethics principles, including confidentiality; demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology. We selected these criteria in our guidance because they are similar to requirements for interpreters under 45 CFR 92.101(b)(3)(i)(A)–(C), when an interpreter is required as a reasonable step to ensure meaningful access to programs or activities by LEP individuals under 45 CFR 92.101(b)(3)(i), which implements section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, (Pub. L 111–148).[95] We note that we did not adopt in our guidance, and do not intend to adopt in this proposed rule, the standard for requiring an interpreter under 45 CFR 92.101(b)(1). Rather, we intend to continue to require that Part D sponsors and MA organizations provide an interpreter for non-English speaking and LEP individuals whenever such an individual contacts the toll-free customer call center under 42 CFR 422.111(h)(1)(iii) and 423.128(d)(1)(iii).

In the final rule titled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' which appeared in the **Federal Register** on April 15, 2011 (76 FR 21431), CMS adopted provisions at §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) to require MA organizations and Part D sponsors to provide interpreters for non–English speaking and LEP individuals who call the plan's toll-free customer call center. In the time since CMS created this requirement for MA organizations and Part D sponsors, there has been a significant increase in timely access to interpreters. For example, CMS data show that interpreters were being made available timely by MA and Part D plans during 66 percent and 60 percent, respectively, of the calls we monitored in 2011; 82 percent and 81 percent, respectively, in 2015; and 88 percent and 86 percent, respectively, in 2021.

In the final rule titled ''Medicare and Medicaid Programs; Contract Year 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,'' which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) (the January 2021 final rule), CMS codified its standards for evaluating compliance by MA and Part D plans with the requirement to provide interpreters for calls to the plans' toll-free call centers by amending §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii). The amendments added requirements that interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

[94] CMS includes this reminder regarding OMH's CLAS standards in our annual HPMS memo detailing the methodology of our call center monitoring studies. For example, see our December 9, 2010 HPMS memo titled ''2011 Part C and Part D Call Center Monitoring and Guidance for Providing Services to Limited English Proficient Beneficiaries;'' our December 16, 2013 HPMS memo titled ''2014 Part C and Part D Call Center Monitoring and Guidance for Timeliness and Accuracy and Accessibility Studies;'' our November 16, 2016 HPMS memo titled ''2017 Part C and Part D Call Center Monitoring and Guidance for Timeliness and Accuracy and Accessibility Studies;'' and our December 16, 2021 HPMS memo titled ''2022 Part C and Part D Call Center Monitoring—Timeliness and Accuracy & Accessibility Studies.''

[95] Recipients of Federal financial assistance are separately obligated to comply with Federal civil rights laws that require recipients to take reasonable steps to ensure meaningful access to their programs and activities by LEP individuals, including through provision of language assistance services that may require interpreters. These laws, enforced by the HHS Office for Civil Rights, include Section 1557 of the Affordable Care Act (42 U.S.C. 18116 and implementing regulation at 45 CFR part 92) (Section 1557), which prohibits, inter alia, discrimination on the basis of race, color, national origin, sex, age, and disability in health programs and activities receiving Federal financial assistance; and Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.* and implementing regulation at 45 CFR part 80) (Title VI), which prohibits discrimination on the basis of race, color, and national origin in programs and activities receiving Federal financial assistance. Regulations implementing Section 1557 set forth specific requirements related to provision of language assistance services, including requirements for interpreter and translation services, when they are required as a reasonable step to ensure meaningful access to programs or activities by limited English proficient individuals. See 45 CFR part 92 for additional information.

These requirements strengthened enrollees' and prospective enrollees' access to interpreters when they call a plan, and thus to information about how to access Medicare-covered benefits.

Building on our previous regulatory proposals to establish and strengthen MA and Part D enrollee access to plan interpreter services, we propose to codify requirements for minimum qualifications for interpreters available to non-English speaking and LEP individuals at MA and Part D call centers. To accomplish this, we are proposing to modify § 422.111(h)(1)(iii)(A) to require MA organizations' interpreters for LEP individuals to meet certain minimum qualifications. As proposed in new paragraphs (A)*(1)* through *(3)* these qualifications include, respectively:

- Adhering to generally accepted interpreter ethics principles, including confidentiality;
- Demonstrating proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and
- Interpreting effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

We propose to establish the same requirements for Part D sponsor interpreters by modifying § 423.128(d)(1)(iii)(A) and adding proposed new paragraphs (A)*(1)* through (A)*(3)* that mirror the proposed changes to § 422.111(h).

We note that on August 4, 2022, HHS published a Notice of Proposed Rulemaking regarding Section 1557 of the Affordable Care Act, which would codify a definition of qualified interpreter similar to what we are proposing here.

We solicit comments on this proposal.

L. Call Center Teletypewriter (TTY) Services (§§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B))

We are proposing to make a technical change to §§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B), which require that MA organizations and Part D sponsors, respectively, connect 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes. Our proposed change is intended to remove any ambiguity that might result from our use of the term ''TTY operator.'' The specific standards found at §§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B) were intended to require that that the caller reach a live person and confirm that said person is able to assist with general Medicare questions or questions about the plan's Part C or Part D benefits within a specific period of time. When an MA organization or Part D sponsor operates their own TTY device and thereby creates a direct TTY to TTY communication, the plan customer representative is also the TTY operator. However, where MA organizations and Part D sponsors utilize telecommunications relay systems, a TTY operator serves as an intermediary between the caller and the plan's customer service representative and is not able to answer the caller's questions about plan benefits.

To ensure that someone utilizing TTY services is connected to a plan customer representative within 7 minutes, we propose to modify §§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B) to instead require the plan's call center establish contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

We solicit comment on this proposal.

M. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (§§ 422.254, 423.265, 423.293, 423.294)

1. Overview and Summary

We propose to add into regulatory text our longstanding prohibition of midyear benefit changes, previously referred to as midyear benefit enhancements (MYBEs) for MA and Part D plans. Specifically, we propose to add regulatory text prohibiting changes to non-drug benefits, premiums, and cost sharing by an MA organization starting after plans are permitted to begin marketing prospective contract year offerings on October 1 (consistent with § 422.2263(a)) of each year for the following contract year and until the end of the applicable contract year. Similarly, we also propose to codify into regulation our longstanding policy prohibiting Part D sponsors from making midyear changes to the benefit design or waiving or reducing premiums, bid-level cost sharing (for example, the cost sharing for an entire formulary tier of Part D drugs), or cost sharing for some or all of a Part D plan's enrollees starting after plans are permitted to begin marketing prospective contract year offerings on October 1 (consistent with § 423.2263(a)) of each year for the following contract year and until the end of the applicable contract year.

Finally, we propose to require Part D sponsors to: (1) refund incorrect collections of premiums and cost sharing, and (2) recover underpayments of premiums and cost sharing. We also propose to establish both a lookback period and timeframe to complete overpayments and underpayment notices, as well as a de minimis threshold for such refunds and recoveries. We solicit comments regarding the addition of similar requirements in MA, specifically establishing a lookback period and de minimis threshold for refunding incorrect collections.

2. Medicare Advantage Prohibition on Midyear Benefit Changes (§ 422.254)

In our proposed rule titled, ''Medicare Program; Establishment of the Medicare Advantage Program'' (69 FR 46865), which appeared in the **Federal Register** on August 3, 2004, and is hereinafter referred to as the ''August 2004 MA proposed rule,'' we acknowledged that in the previous Medicare+Choice program, organizations were permitted to offer MYBEs to existing benefit packages. We proposed to discontinue this policy, noting how we believed that it would no longer be appropriate to allow MA organizations to offer new plans or change an existing plan's benefits midyear because such revised (or new) MA plans would not reflect the bids which were approved during the normal approval process (as set forth in 42 CFR part 422, subpart K). We explained how MYBEs are de facto adjustments to benefit packages for which bids were submitted by MA organizations based on their estimated revenue requirements. Specifically, we expressed concern that allowing MYBEs could render the bid meaningless (69 FR 46899).

In our final rule titled, ''Medicare Program; Establishment of the Medicare Advantage Program'' (70 FR 4640), which appeared in the **Federal Register** on January 28, 2005, and is hereinafter referred to as the ''January 2005 MA final rule,'' we adopted the MYBE policy described in the August 2004 MA proposed rule with modifications in response to comments from MA organizations requesting flexibility regarding MYBEs in order to improve enrollee experiences or adjust for unforeseen errors, under certain circumstances. Specifically, we adopted a limited MYBE policy to (1) permit a MYBE to be effective no earlier than July 1 of the contract year, and no later than September 1 of the contract year; (2) prohibit MA organizations from submitting MYBE applications later than July 31 of the contract year; and (3) require 25 percent of the value of the MYBE to be retained by the government.

The policy also required the MA organization to submit a revised bid and supporting documentation about how revenue requirements were overstated in the bid submitted for the contract year. (70 FR 4640) However, we noted that this was an interim policy for the initial years of the competitive bidding system and that we would review the continuing need for the policy.

Subsequent to the January 2005 MA final rule, we issued the proposed rule titled, ''Medicare Program; Prohibition of Midyear Benefit Enhancements for Medicare Advantage Organizations Offering Plans in Calendar Year 2007 and Subsequent Calendar Years'' (71 FR 52014), which appeared in the **Federal Register** on September 1, 2006, and is hereinafter referred to as the ''September 2006 MA proposed rule.'' There, we proposed that, beginning with CY 2007, MA organizations would not be permitted to make any midyear changes in benefits, premiums, or cost sharing, even under the circumstances in which these types of changes were permitted previously. We finalized this policy in the final rule titled, ''Medicare Program; Prohibition of Midyear Benefit Enhancements for Medicare Advantage Organizations'' (73 FR 43628), which appeared in the **Federal Register** on July 28, 2008, and is hereinafter referred to as the ''July 2008 final rule.''

While previous rules referred to these changes as ''midyear benefit enhancements,'' or MYBEs, we are proposing to instead use the term ''midyear benefit changes'' to better clarify that all changes (enhancements or reductions) to non-prescription drug benefits, premiums, and cost sharing are prohibited for MA plans, consistent with the scope of our prior rulemaking. However, we are not proposing to prohibit MA plans from revising plan rules, such as prior authorization or referral policies, or from making network changes; the rules in § 422.111(d) regarding notice to enrollees about changes in plan rules are not proposed to be changed. Please see section III.D. of this proposed rule for our proposal to revise the rules in § 422.111(e) concerning notice of a change in an MA plan's provider network. Additionally, this proposal, if finalized, would not prohibit MA plans from covering required changes or additions to basic benefits, that is Part A and Part B benefits that all MA plans must cover, when those changes or additions to basic benefits are the result of a change in the law, such as newly enacted legislation, or rulemaking or a National Coverage Determination; such changes are required to be made by MA plans, subject to section 1852(c)(5) of the Act and § 422.109 which provide for the Medicare FFS program to cover certain changes in Part A and Part B benefits. Our proposal encompasses other changes in MA non-drug, premiums and any cost sharing outside of required changes or exceptions we have noted here. Consequently, we hereinafter refer to these alterations as ''midyear benefit changes'' (MYBCs).

Although we finalized the policy in the July 2008 final rule and have accordingly enforced it ever since, we now propose to add regulatory text explicitly prohibiting MYBCs and specifying when such changes will be prohibited. Specifically, we propose to clarify in regulatory text that any changes to non-prescription drug benefits, cost sharing, and premiums are prohibited starting after plans are permitted to begin marketing prospective contract year offerings on October 1 of each year for the following contract year (consistent with § 422.2263(a)) and through the end of the applicable contract year. This means that after marketing is permitted to begin for the 2024 contract year, MA organizations must offer the benefits described in approved bids through the end of the 2024 contract year. In other words, MA organizations are prohibited in this scenario from changing the benefits, cost sharing and premiums in their approved bids from October 1, 2023 until December 31, 2024, except for modifications in benefits required by law.

Consistent with our current practice as described in the July 2008 final rule, prohibiting changes after marketing is permitted to begin provides MA organizations the flexibility to make changes during the bidding process when permitted by CMS to remain in compliance with the requirements set forth at § 422.254(b), while also maintaining the integrity of the bidding process.

We note that per § 422.2263 following the start of marketing on October 1 of each year, MA organizations may begin to market and publicize their plan offerings for the following contract year, such that organizations may compare their approved plans against competitors in order to make advantageous changes. As we noted the August 2004 and September 2006 MA proposed rules, allowing MYBCs undermines the integrity of the bidding process as it allows MA organizations to alter their benefit packages after the bidding process is complete. Further, MA organizations may use MYBCs to misrepresent their actual costs and noncompetitively revise their benefit packages later in the year (69 FR 46899, 70 FR 4301, 71 FR 52016).

Altering an approved plan to include new benefits after marketing has started may also give MA organizations an unfair advantage over competitors when beneficiaries are selecting their plans during the initial coverage elections period (ICEP). We articulated in the July 2008 final rule that we believe newly age-eligible enrollees are attractive to MA organizations because of their relatively low utilization, as these individuals are new to the program and tend to be healthier (73 FR 43631). Therefore, to prevent MA organizations from inappropriately changing bids to appeal to low-utilization enrollees, an MA organization must provide the benefits described in the MA organization's final plan benefit package (PBP) (as defined in § 422.162(a)) until the end of the applicable contract year. The July 2008 final rule reiterated these points. Despite the issuance of the July 2008 final rule, however, we have continued to receive inquiries from MA organizations requesting changes to PBPs after the contract year has begun.

We note that MYBCs of this nature would also violate the uniformity requirements set forth at § 422.100(d)(ii), which requires that an MAO must offer their plan to all beneficiaries in a service area ''at a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2).'' Altering the non-prescription drug benefits, premiums, or cost sharing midyear violates this requirement, even if the new benefit, premium, or cost sharing is offered to all of the plan's enrollees, as some enrollees would have paid for such benefits, premiums, or cost sharing already, and would not be eligible for reimbursement of these costs. In other words, some plan enrollees would have paid higher or lower amounts for the same benefits or services than other enrollees who paid depending on when the MYBC was put in effect.

On May 22, 2020, we issued guidance in a Health Plan Management System (HPMS) memorandum titled ''Information Related to Coronavirus Disease 2019—COVID–19'' (hereinafter referred to as the ''2020 COVID–19 guidance,'' and available at *https://www.cms.gov/files/document/covid-19-updated-guidance-ma-and-part-d-plan-sponsors-may-22-2020.pdf*) which specified changes in policy for MA Organizations following the declaration of the COVID–19 Public Health Emergency (PHE). Due to the extraordinary nature of the PHE and its

impact on Medicare eligible individuals and the disabled and elderly population generally, the 2020 COVID–19 guidance allowed for relaxed enforcement of the prohibition on MYBCs, with certain limitations. Specifically, MYBCs would be allowed when such MYBCs are: (1) provided in connection with the COVID–19 PHE; (2) beneficial to enrollees; and (3) provided uniformly to all similarly situated enrollees. Additionally, we permitted MA organizations to implement additional or expanded benefits that address issues or medical needs raised by the COVID–19 PHE, and provided examples like covering meal delivery or medical transportation services to accommodate the efforts to promote social distancing during the COVID–19 PHE. We further noted in our January 14, 2022 memo entitled ''Coronavirus Disease 2019 (COVID–19) Permissive Actions Extended in Contract Year 2022'' that we would exercise our enforcement discretion until the conclusion of the COVID–19 PHE. Despite the current COVID–19 guidance, MA organizations have continued to request changes to approved plan bids which are not consistent with the parameters specified in such guidance.

While our proposed addition to the regulation text is not intended to supersede the 2020 COVID–19 guidance (should it remain in effect through the 2024 calendar year), we propose to add regulatory text to solidify longstanding policy to prohibit MYBCs starting after the plan has begun marketing prospective contract year offerings on October 1 of each year for the following contract year and until the end of the applicable contract year as a means to provide clarification for MA organizations and maintain the integrity of the bidding process. As discussed previously, this prohibition includes exceptions for changes in benefits required by applicable law.

Employer Group Waiver Plans (EGWPs) exclusively enroll the members of the group health plan sponsored by the employer, labor organization (that is, union) or trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations; these plans generally have ''800 series'' MA contracts with CMS. These EGWPs are not currently subject to this prohibition on MYBCs under existing CMS waivers for EGWPs. However, an MA organization is subject to the prohibition on MYBCs if the MA organization offers an MA plan that that enrolls both individual beneficiaries and employer or union group health plan members, (that is, a plan open to general enrollment); for those types of plans, the employer or union sponsor may make mid-year changes to offer or change only non-MA benefits that are not part of the MA contract (that is, are not basic benefits or MA supplemental benefits). (*See* 73 FR 43630 and Chapter 9, section 20.3, of the Medicare Managed Care Manual, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c09.pdf.*)

Because this proposal would add regulatory text regarding the MYBC policy which has already undergone notice and comment rulemaking, and does not change the scope of that prior non-codified rule, this provision is technical in nature, and there is no paperwork burden. Additionally, this provision will not impact the Medicare Trust Fund.

We solicit comment on these proposals.

3. Part D Prohibition on Midyear Benefit Changes (§ 423.265)

Section 1860D–11(d) of the Act grants CMS the authority to review information pertaining to Part D sponsors' proposed plans and negotiate terms and conditions of the proposed bid and proposed plan with Part D sponsors. Section 1860D–11(e) of the Act grants CMS the authority to approve Part D sponsors' proposed plans. To implement sections 1860D–11(d) and (e) of the Act, we proposed regulations at § 423.272 in our proposed rule titled ''Medicare Program; Medicare Prescription Drug Benefit'' (69 FR 46631), which appeared in the **Federal Register** on August 3, 2004 (hereinafter referred to as the ''August 2004 Part D proposed rule''). We finalized these regulations in our final rule titled ''Medicare Program; Medicare Prescription Drug Benefit'' (70 FR 4193), which appeared in the January 28, 2005 issue of the **Federal Register** (hereinafter referred to as the ''January 2005 Part D final rule'').

In response to comments to our August 2004 Part D proposed rule regarding the authority to enter into bid-level negotiation with Part D sponsors, and as was discussed in section III.M.2. of this proposed rule, we stated in our January 2005 Part D final rule that in order to maintain the integrity of the bidding process, we believed it was not appropriate to allow either MA organizations or Part D sponsors to waive premiums or offer midyear benefit enhancements, as they would be de facto adjustments to benefit packages for which bids were submitted earlier in the year. We also stated that these adjustments would be de facto acknowledgement that the revenue requirements submitted by the plan were overstated, and further, that allowing premium waivers or midyear benefit enhancements would render the bid meaningless (70 FR 4301).

As noted in section III.M.2. of this proposed rule, we previously referred to these changes as ''midyear benefit enhancements,'' or MYBEs, and it stands to reason that midyear benefit changes, whether enhancements or reductions, are equally problematic from the perspective of bid integrity. Therefore, we hereinafter refer to these alterations as ''midyear benefit changes,'' or MYBCs.

Additionally, section 1860D–11(e)(2)(C) of the Act requires that the bid reasonably and equitably reflect the revenue requirements of the expected population for the benefits provided under the plan. Therefore, in addition to indicating that the plan bid was overstated and rendering the bid meaningless, waiving or reducing the premiums, cost sharing, or both, that are reflected in the approved bid would indicate that the amounts provided in the bid were not necessary for the provision of coverage.

We draw a distinction here between changes in ''bid-level'' cost sharing (for example, the cost sharing associated with an entire tier of drugs) and changes in the cost sharing for an individual drug (for example, when such drug moves from one already approved tier of the benefit to another already approved tier of the benefit). As is discussed further in section III.Q. of this proposed rule, section 1860D–4(b)(3)(E) of the Act, as codified at § 423.120(b)(5),[96] requires that Part D sponsors provide appropriate notice before any removal of a covered Part D drug from a formulary and ''any change in the preferred or tiered cost-sharing status'' of such a drug. Thus, the statute contemplates midyear changes in cost sharing of individual formulary drugs. Consequently, since the beginning of the Part D program, we have allowed formulary changes that result in changes to the cost sharing for individual drugs (for example, moving a single drug to a different cost-sharing tier), but have declined to permit Part D sponsors to change their benefit designs or waive or reduce premiums, ''bid-level'' cost sharing (for example, the cost sharing

[96] We propose organizational changes to the existing regulations to streamline them and improve their clarity, which would include two subparagraphs on approval of changes and provision of notice to appear, respectively, at § 423.120(e) and (f).

associated with an entire tier of drugs), or cost sharing (for some or all enrollees) once plans are permitted to market for the following contract year (on October 1, consistent with § 423.2263(a)) on the grounds that such activities would be inconsistent with the CMS-approved bid.

Additionally, section 1860D–2(a) of the Act defines qualified prescription drug coverage to mean standard (Defined Standard or Actuarially Equivalent Standard) prescription drug coverage or alternative prescription drug coverage (with at least actuarially equivalent benefits) and access to negotiated prices in accordance with section 1860D–2(d) of the Act. In our proposed rule titled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (74 FR 54633), which appeared in the October 22, 2009 issue of the **Federal Register** (hereinafter referred to as the ''October 2009 proposed rule'') we further interpreted section 1860D–2(a) of the Act as requiring the provision of uniform premium and benefits. We codified these requirements in our regulations at § 423.104(b) in our final rule titled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (75 FR 19677), which appeared in the **Federal Register** on April 15, 2010.

In addition to violating the bid requirements, as we noted in the preamble of the October 2009 proposed rule, a Part D sponsor's waiver of cost sharing midyear also violates the uniform benefit requirements, because doing so results in plans not providing the same coverage to all eligible beneficiaries within their service area (74 FR 54690). The CMS-approved benefit cannot be varied for some or all of the plan's enrollees midyear, as that would violate the uniform benefit provisions set forth in § 423.104(b). Even if the plan changes the benefit midyear for all of the plan's enrollees, this still violates the uniform benefits provision because some of the plan's enrollees would still have paid for benefits prior to the change. We note that during the COVID–19 PHE, CMS provided for specific flexibilities by Part D sponsors to ensure adequate pharmacy access that would otherwise violate the uniform benefit provisions. CMS exercised its enforcement discretion to temporarily permit Part D sponsors to fully or partly waive cost sharing for covered Part D drugs with medically accepted indications for COVID–19.

To clarify these points for all parties, we propose to codify in regulation our longstanding subregulatory policy at new paragraph § 423.265(b)(5) which would require that once a Part D sponsor is permitted to market prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), that is, as of October 1, it shall not change, and therefore, must provide, the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182(a)) for the contract year without modification, except where a modification in benefits is required by law.

Additionally, we have been monitoring compliance with this policy via our Part D Bid review and approval process, consistent with § 423.272. Consequently, there is no additional paperwork burden associated with codifying this longstanding subregulatory policy.

We solicit comment on this proposal.

4. Failure To Collect and Incorrect Collections of Part D Premiums and Cost Sharing Amounts (§§ 423.293 and 423.294)

As was described in section III.M.3. of this proposed rule, Part D sponsors' waiver of cost sharing or premiums would violate the uniform premium and benefit requirements of section 1860D–2(a) of the Act and § 423.104(b). Similarly, Part D sponsors' incorrect collections of cost sharing and premiums also could have the effect of making the benefit non-uniform.

The current regulatory language at § 423.104(b) mirrors the language at § 422.100(d)(1) and (2)(i) with regard to uniform premiums and cost sharing. However, although the MA program adopted language at § 422.270 to address incorrect collections of premiums and cost sharing in the January 2005 MA final rule, the regulations in Part 423 do not address Part D sponsor requirements regarding incorrect collections of premiums and cost sharing. We intend to bring the Part D requirements into alignment with the existing MA requirements for incorrect collections, as well as establish new requirements regarding failure to collect premiums and cost sharing amounts. Therefore, for incorrect collections, we propose to codify requirements at a new § 423.294 that would be similar to the MA program requirements at § 422.270. We also propose to codify new requirements regarding failure to collect premiums and cost sharing amounts at § 423.294. Finally, we solicit comment regarding adding a similar policy to add new requirements for MAOs regarding failure to collect premiums and cost sharing in § 422.270.

Our proposed Part D requirements would require a Part D sponsor to make a reasonable effort to collect monthly beneficiary premiums under the timing established in § 422.262(e) (made applicable to Part D premiums in § 423.293(a)(2)) and ensure collection of cost sharing at the time a drug is dispensed. If for some reason the Part D sponsor fails to collect or ensure collection in a timely manner, the Part D sponsor would be required to make a reasonable effort to bill for and recover the premium or cost sharing amount after the fact. Any adjustments to the premium or cost sharing amount that occur based on subsequently obtained information would be made within the timeframe for coordination of benefits as established at § 423.466(b), which is 3 years from the date on which the monthly premium was due or on which the prescription for a covered Part D drug was filled. A Part D sponsor could decline to attempt to recover an amount if it is below a de minimis amount, as detailed below.

Our proposed Part D requirements would also require a Part D sponsor to make a reasonable effort to identify any amounts incorrectly collected from its Medicare enrollees, or from others on behalf of affected enrollees. Sponsors would have to issue refunds during the same 3-year timeline applicable to recoveries, as described previously, and need not issue refunds if they are below a de minimis amount.

Our proposed Part D requirements would differ from the existing requirements at § 422.270 in the following ways. The first modification to our proposed requirements for Part D sponsors is that we propose to clarify that the 3-year lookback period established in § 423.466(b) for coordination of benefits applies to retroactive claim or premium adjustments that result in refunds and recoveries at § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively. Currently, a Part D sponsor is required to process retroactive claims adjustments within 45 days of receiving complete information, per § 423.466(a), and there is no requirement for the timing of retroactive premium adjustments. While § 423.466(b) allows 3 years for coordination of benefits, there is currently no limit in the regulation for how far back retroactive premium adjustments or claims adjustments unrelated to coordination of benefits must be made. For example, if a Part D sponsor in 2022 identifies an error in their prior years' drug pricing files that resulted in beneficiaries being charged

incorrect cost sharing from 2015 to 2020, the current regulation might require them to refund and/or recover amounts for prescriptions beneficiaries received as long as seven years ago. This is not only inconsistent with our coordination of benefits requirements, which would only require adjustments for the past 3 years, but is potentially confusing to beneficiaries. By proposing to establish a 3-year lookback period in § 423.294(b)(2) and (4) and § 423.294(c)(2), we would align the timeframe established in § 423.466(b) for coordination of benefits with the timeframe for premium adjustments and claims adjustments unrelated to coordination of benefits. Not only would this 3-year period coincide with the timeframe established in § 423.466(b) for coordination of benefits with State Pharmaceutical Assistance Programs (SPAPs) and other entities, including beneficiaries and others paying on the beneficiaries' behalf, but it would also align with the timeframe for redeterminations in § 423.1980(b) and (c). A Part D sponsor would not be required to make a premium or claims payment adjustment if more than 3 years has passed from the date of service, just as a Part D sponsor is required to coordinate benefits for a period of 3 years.

In section IV.N. of this proposed rule, we are proposing to codify at § 423.44(d)(1)(v) current policy that excepts certain prescription drug plan (PDP) members from being disenrolled for failure to pay plan premiums. Additionally, as also discussed at section IV.N. of this proposed rule, we propose at revised § 423.44(d)(1)(v) a disenrollment exception if the Part D sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer. We also (1) expect Part D sponsors to issue collection notices and, (2) consistent with the requirements at § 423.44, require Part D sponsors to make a reasonable attempt at collection, notwithstanding the requirements at § 423.44 for involuntary disenrollment. Nonetheless, we would not expect a Part D sponsor to disenroll a Part D enrollee for such Part D sponsor's failure (when the plan made the error) to collect the proper payment and subsequent failure to collect an underpayment. Section 50.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual also provides that we expect a Part D sponsor to have billed the Part D enrollee prior to the start of the grace period *for the actual premium amount due* (emphasis added), with such notice/bill specifying the due date for that amount.

Additionally, specific to cost sharing, under current regulations at § 423.566(b)(5), a decision on the amount of cost sharing for a drug constitutes a coverage determination. If a claim adjudicates at an incorrectly low amount, or if other actions by a Part D sponsor result in the Part D enrollee being asked to pay an incorrectly low cost-sharing amount, such adjudication or action is a coverage determination. If the Part D sponsor becomes aware of the error, the Part D sponsor would reopen the previously adjudicated coverage determination consistent with the reopening rules at §§ 423.1980 through 423.1986. If the Part D sponsor issues an adverse revised determination, the notice must state the rationale and basis for the reopening and revision and any right to appeal.

Second, at § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively, we propose to clarify that the 45-day timeframe in § 423.466(a) applies to the processing of refunds and recoveries for both claims and premium adjustments. This would make the timeframes for the refund or recovery of premium adjustments the same as for claims adjustments and for refunds and recoveries related to the low-income subsidy program, which under § 423.800(e) are the same as the requirements of § 423.466(a). In other words, whenever a Part D sponsor receives, within the 3-year lookback period, information that necessitates a refund of enrollee overpayment of premiums, cost sharing, or both, or recovery of underpayments of premiums, cost sharing, or both, the Part D sponsor would be required to issue refunds or recovery notices within 45 days of the Part D sponsor's receipt of such information. Nothing in this proposal would alter the requirements of § 423.293(a)(4) with respect to the options a Part D sponsor must provide Part D enrollees for retroactive collection of premiums.

We note we are not proposing any changes to the Medical Loss Ratio (MLR) requirements under §§ 422.2420(c) and 423.2420(c), which provide that uncollected premiums that could have been collected still count as revenue.

The final difference between our proposed requirements for Part D sponsors and existing Part C requirements is that we propose to apply a de minimis amount, calculated per Prescription Drug Event (PDE) transaction or, for premium adjustments, per month, for these refunds and recoveries. As proposed at § 423.294(b) and (c)(1), if a refund or recovery amount falls below the de minimis amount set for purposes of § 423.34(c)(2) for low income subsidies (currently at $2 for 2022), the Part D sponsor would not be required to issue a refund or recovery notice. For instance, if a sponsor in 2024 discovered that it had charged incorrect premiums amounts to certain beneficiaries for a 12-month period from January through December of 2022 and the de minimis amount for 2024 is $2, the sponsor would not have to issue recovery notices to any beneficiary who owed $24 or less total for the 12-month period. This proposal clarifies that the existing coordination of benefits (COB) requirements in § 423.466 encompass payment adjustments. As such, the proposed timeframe for the proposed requirements to refund or recover incorrectly collected cost sharing and premium amounts would not result in any additional costs to Part D sponsors, Part D enrollees, or the government. Conversely, because there was previously no historical limit or threshold for such refunds and recoveries, establishing both a 3-year lookback period and de minimis amount would remove significant administrative burden on plan sponsors and the government, particularly in circumstances where the amount to be refunded or recovered is less than the postage required to provide a refund or recovery notice. Consequently, this provision would not impact the Medicare Trust Fund, and there would be no additional paperwork burden, as recovery notices are already required under § 423.466, and § 423.293 already provides a process for the retroactive collection of premiums.

Current MA regulations set forth at § 422.270 do not contain requirements for MA organizations to refund or recover incorrect collections of cost-sharing or premiums with regard to a de minimis amount or a lookback period. On the contrary, § 422.270(b) states that an MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf. With regard to timing of recovering underpayments when an enrollee is not at fault, § 422.262(h) states an enrollee may make payments by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. We solicit comments on

adding requirements regarding a de minimis amount and lookback periods for recovering or refunding incorrect collections in MA to that mirror proposed requirements in Part D.

We are also proposing a technical change to the regulation text related to the Part D retroactive collection of monthly beneficiary premiums. We propose to amend § 423.293(a)(4) by replacing ''Medicare Advantage organization'' with ''Part D sponsor'' to be consistent with the terminology used in the rest of § 423.293.

We solicit comment on these proposals.

5. Summary of Proposals and Comment Solicitation

In summary, we are proposing to:

- Add § 422.254(a)(5) to add regulatory text regarding the requirement that starting after an MA organization is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 422.2263(a)), it may not change, and therefore must provide, the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 422.162(a)) for the contract year without modification, except where a modification in benefits is required by law. This proposed prohibition on changes would apply to cost sharing and premiums as well as benefits;
- Add § 423.265(b)(5) to codify the requirement that starting after a Part D sponsor is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), it may not change, and therefore, must provide, the benefits described in its CMS-approved PBP (as defined at § 423.182) for the contract year without modification, except where a modification in benefits is required by law;
- Make a technical correction at § 423.293(a)(4) to replace ''Medicare Advantage organization'' with ''Part D sponsor''; and
- Add new § 423.294 to codify requirements regarding failure to collect, and incorrect collections of, enrollee premiums and cost sharing for Part D sponsors, including:

++ Specifying in proposed § 423.294(a) that failure to collect premiums and cost sharing, or incorrect collections of premiums or applicable cost sharing, violates the uniform benefit provisions at § 423.104(b);

++ Applying a 3-year lookback period for the identification of applicable refunds and recoveries at the proposed § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively;

++ Applying a 45-day period to issue applicable refunds and recovery notices at the proposed § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively;

++ Specifying at proposed § 423.294(b)(3) the refund methods for amounts incorrectly collected and other amounts due; and

++ Specifying at proposed § 423.294(b) and (c)(1) a de minimis amount for applicable refunds and recoveries.

We solicit comment regarding adding new requirements (specifically adding a de minimis amount and lookback period) in the MA regulations regarding failure to collect premiums and cost sharing in § 422.270 to align with the proposed changes for Part D sponsors described in this section of the proposed rule.

We solicit comment on these proposals and policy questions.

N. Clarify Language Related to Submission of a Valid Application (§§ 422.502 and 423.503)

1. Overview and Summary

We are proposing to amend the language in § 422.502 and § 423.503 to codify CMS's authority to decline to consider a substantially incomplete application for a new or expanded Part C or D contract. We are also proposing to codify criteria for determining that an application is substantially incomplete.

Since we began our contracting efforts under the Medicare Modernization Act of 2003 in 2005 in preparation for the statute's 2006 effective date, we have established strict deadlines for the initial submission of applications for an entity to qualify as an MAO or Part D sponsor for a new contract, expansion of a service area of an existing contract, or to offer an MA SNP and the resubmission of materials needed to cure identified deficiencies. These deadlines are established annually in our Parts C and D applications, in accordance with §§ 422.501 and 423.502. Consistent with that operational policy, we do not review applications that are submitted after the established deadline. Entities submitting applications after the deadline do not receive a new or expanded Part C (either a general MA contract or approval to offer a SNP) or D contract for the following benefit year. An entity missing the deadline also does not receive a notice of intent to deny under §§ 422.502(c)(2) or 423.503(c)(2) and is not entitled to a hearing under §§ 422.660 or 423.650.

CMS noted in the final rule which appeared in the **Federal Register** on April 15, 2011 titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' (76 FR 21431), hereafter referred to as the April 2011 final rule, that, in order to meet the submission deadline, some entities had submitted applications that were so lacking in required information as to fail to constitute a valid submission (76 FR 21527). If permitted to proceed with such an application, the entity would be able to complete their application by taking advantage of two later opportunities (including the period following the notice of intent to deny) to cure deficiencies. These ''placeholder'' applications would allow entities more time to submit complete applications than applicants that submitted complete applications by the application deadline. We stated in the preamble to the April 2011 final rule that we considered this an abuse of the application review process and have therefore treated such substantially incomplete applications as invalid since the enactment of the April 2011 final rule.

In the April 2011 final rule, we stated that we believed that substantially incomplete applications were submitted in part because of confusion about our authority to enforce the application deadline (76 FR 21527). This confusion was likely a result of the then-effective provisions of §§ 422.502(c)(2)(i) and 423.503(c)(2)(i), which stated that CMS would provide an applicant a notice of intent to deny when the entity ''has not provided enough information to evaluate the application.'' We stated that we had intended this language to afford an entity that had made a good faith effort to complete an application the opportunity to provide materials necessary to cure discrete application deficiencies, not to provide an unintended protection and additional time to entities that submitted ''placeholder'' applications. In order to correct this misunderstanding and to allow us to enforce our application submission deadline, CMS amended the regulation to remove the quoted language in §§ 422.502(c)(2)(i) and 423.503(c)(2)(i). Since that time, we have treated substantially incomplete applications as invalid applications that are not entitled to a notice of intent to deny or a hearing under §§ 422.502(c)(2) or 423.503(c)(2) or entitled to a hearing under §§ 422.660 or 423.650. While we notify organizations that submit substantially incomplete applications that we consider their application to be substantially incomplete and therefore invalid, that notification is for

informational purposes only and is not a notice of intent to deny under §§ 422.502(c)(2) and 423.503(c)(2).

CMS is proposing to codify its longstanding policy with respect to substantially incomplete applications.

2. Discussion (§§ 422.502 and 423.503)

We propose to modify §§ 422.502 and 423.503 by adding new paragraphs (a)(3) and (a)(4), respectively, regarding substantially incomplete applications. At §§ 422.502(a)(3)(i) and 423.503(a)(4)(i), CMS proposes to codify that it does not evaluate or issue a notice of determination as described in §§ 422.502(c) and 423.503(c), respectively, when an entity submits a substantially incomplete application. This proposed modification to the regulatory text is consistent with the longstanding policy to treat substantially incomplete applications as if they were not submitted by the application deadline and therefore the submitting entity is not entitled to review of its submitted material or an opportunity to cure deficiencies.

We also propose at §§ 422.502(a)(3)(ii) and 423.503(a)(4)(ii) to codify our definition of a substantially incomplete application as one that does not include responsive materials to one or more sections of its MA or Part D application, respectively. Pursuant to §§ 422.501(c) and 423.502(c), CMS requires entities seeking to qualify as an MAO (or to qualify to offer a SNP) and/or Part D sponsor to submit an application in the form and manner required by CMS. Applications for service area expansions are subject to the same rules and review processes as we treat the expansion of a plan service area as a new application for a new area. We prescribe the form and manner in an application published annually. This application is subject to the Paperwork Reduction Act review process. The form and manner vary somewhat from year to year, but generally include several sections that require an entity to demonstrate compliance with specific categories of program requirements. For instance, Part D applications for new Part D contracts include: (1) a series of attestations whereby the applicant agrees that it understands and complies with various program requirements; (2) a contracting section that requires entities to demonstrate compliance with Part D requirements by submitting certain first tier, downstream, and related entity contracts and network pharmacy templates; (3) a network section that requires entities to submit lists of contracted pharmacies that meet geographic and other access requirements; (4) a program integrity section that requires entities to submit documentation that they have documented and implemented an effective compliance program as required by § 423.504(b)(vi); and (5) a licensure and solvency section that requires entities to meet applicable licensure and fiscal solvency requirements. MA applications require substantially similar information related to the operation of an MA plan, and SNP applications include additional sections related specifically to SNP requirements for the type of SNP the applicant seeks to offer. Consistent with past practice, CMS proposes to treat an application that does not include required content or responsive materials for one or more of these sections as substantially incomplete. In our assessment, applications that fail to include significant amounts of responsive materials, including failing to include required content or responsive material for any section of the application, in materials submitted by the application submission deadline are merely submitting placeholder applications that do not merit additional opportunities to meet CMS requirements.

An example of a Part D application that would be incomplete and therefore excluded from further consideration under the proposed rule is one that failed to upload a retail pharmacy list that would allow CMS to determine whether it met pharmacy access requirements. This would include failure to submit a list at all, submitting a list containing fictitious pharmacies, or submitting a list that contained so few pharmacies that CMS could only conclude that no good faith effort had been made to create a complete network. CMS would also deem as substantially incomplete any application that failed to submit any executed contracts with first tier, downstream, or related entities that the applicant had identified as providing Part D services on its behalf.

An example of a MA application that would be incomplete and therefore excluded from further consideration is one that failed to upload either a State license or documentation that the State received a licensure application from the applicant before the CMS application due date. Another example of an incomplete MA application would be one that failed to upload network adequacy materials, including failing to submit network lists for designated provider types, submitting fictitious providers, or submitting a list that contained so few providers that CMS could only conclude that no good faith effort had been made to create a complete network.

An example of a SNP application that would be incomplete and therefore excluded from further consideration is one that failed to upload a model of care (MOC) that would allow CMS to determine whether or not it met MOC element requirements. This would include failure to submit MOC documents at all or submitting incomplete documents that did not contain all of the required MOC elements.

Finally, we propose at §§ 422.502(a)(3)(iii) and 423.503(a)(4)(iii) to explicitly state that determinations that an application is substantially incomplete are not contract determinations as defined at §§ 422.641 and 423.641, respectively. Because they are not contract determinations, determinations that an application is substantially incomplete are not entitled to receipt of specific notices or appeal under Parts 422 and 423, subpart N. CMS has consistently taken this position when determining an application is substantially incomplete because a submission that is so incomplete as to not be deemed a valid application did not meet the application deadline and cannot be meaningfully reviewed. Nevertheless, a few entities have used the contract determination hearing process to appeal CMS's determination that they did not submit a substantially complete application by the application deadline. In such cases, the Hearing Officer has ruled that such determinations were not contract determinations entitled to hearings under §§ 422.660 and 423.650.

CMS does not believe that our proposed regulatory provisions at §§ 422.502(a)(3)(i) and 423.503(a)(4)(i) will have a significant impact on the Part C or D programs. Only a handful of entities have attempted to submit substantially incomplete applications in recent years. CMS believes that codifying our treatment of substantially incomplete applications will further discourage entities from submitting placeholder applications and ensure that materials submitted by the application deadline represent entities' good faith efforts to meet application requirements.

We solicit comment on this proposal.

3. Summary of Proposals

In summary, we are proposing to:

- Add §§ 422.502(a)(3) and 423.503(a)(4) to codify CMS's policy of not evaluating or issuing a notice of determination as described in §§ 422.502(c) or 423.503(c) when an

entity submits a substantially incomplete application;

- Specify at the proposed §§ 422.502(a)(3)(ii) and 423.503(a)(4)(ii) that a substantially incomplete application is one that does not include responsive materials to one or more sections of the application; and
- Specify at the proposed §§ 422.502(a)(3)(iii) and 423.503(a)(4)(iii) that a determination that an entity submitted a substantially incomplete application is not subject to the appeals provisions of Part 422 and 423, subpart N.

We solicit comment on these proposals.

O. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

1. Standing Request for Translated Materials and Materials in Accessible Formats Using Auxiliary Aids and Services

In accordance with our authority under sections 1851(h), 1851(j), 1852(c), 1860D–1(b)(1)(B)(vi), 1860D–4(a), and 1860D–4(l) of the Act, §§ 422.2267(a)(2) and 423.2267(a)(2) of the regulations require MA organizations and Part D sponsors to translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. This threshold is based on the Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (67 FR 41455 through 41472, published in June 2002) that implemented Executive Order 13166 (signed in August 2000). In addition, per § 417.428, cost plans with contracts under section 1876 of the Act must follow the same marketing and communication regulations; we apply the same standards to cost plans under this regulation based on our authority in section 1876(i)(3)(D) of the Act. Each fall, we release an HPMS memorandum announcing that plans can access in the HPMS marketing review module a list of all languages that are spoken by 5 percent or more of the population for every county in the U.S.[97] In the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drugs Benefit Program; Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency final rule, which appeared in the May 9, 2022 **Federal Register** (87 CFR 27704) (hereinafter referred to as the May 2022 final rule), we also adopted a requirement that MA and Part D plans use a multi-language insert (MLI), which informs the reader, in the top fifteen languages used in the U.S., as well as any additional non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area, that interpreter services are available for free. In accordance with §§ 422.2267(e)(31) and 423.2267(e)(33), the MLI must be included with all CMS required materials provided to current or prospective enrollees. As discussed in the May 2022 final rule, CMS considers the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary decision making process; ensuring beneficiaries with limited English proficiency are aware of and are able to access interpreter services therefore provides a clear path for this portion of the population to properly understand and access their benefits (87 FR 27821).

In addition, MA organizations and Part D sponsors must comply with section 504 of the Rehabilitation Act of 1973, section 1557 of the Affordable Care Act, and implementing regulations at 45 CFR part 92. The regulations at 45 CFR 92.102(b) require plans to provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. Section 92.102(b)(1) defines the auxiliary aids and services for plans to provide to enrollees. For written materials this includes but is not limited to braille, large print, data/audio files, relay services, and TTY communications. We further explained the obligation of plans to provide accessible communications for individuals with disabilities in an August 30, 2017, Health Plan Management System memorandum titled, ''Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557).'' [98]

However, CMS has learned from oversight activities, enrollee complaints, and stakeholder feedback that enrollees often must make a separate request each time they would like a material in an alternate language or need auxiliary aids and services. In addition, during CMS program audits and oversight activities we have found that special needs plans (SNPs) do not always translate individualized care plans (ICPs) into enrollees' preferred languages, even when the enrollee has expressed a preference for translation as part of completing the health risk assessment. To address these issues, we are proposing here, based on our authority under the Medicare statute, to adopt regulations to impose additional Medicare marketing and communications standards on plans to ensure access to important information and materials for individuals who have limited English proficiency or need auxiliary aids or services.

The materials required under §§ 422.2267(e) and 423.2267(e) and ICPs are vital to how individuals access services and make decisions about their health care. These materials furnish important information about coverage and benefits under Medicare health and drug plans. We believe this proposal will make it easier for beneficiaries to understand the full scope of available Medicare benefits (as well as Medicaid benefits available through the D–SNPs, where applicable), increasing their ability to make informed health care decisions, and promote a more equitable health care system by increasing the likelihood that MA enrollees have access to information and necessary health care.

The U.S. Census Bureau's 2019 American Community Survey (ACS) 1-year estimates show that 12.2 percent of individuals 65 years of age and older speak a language other than English in the home.[99] Nearly 8 percent of Medicare beneficiaries are individuals with limited English proficiency, many of whom need an interpreter or other language assistance to communicate

[97] CMS released the contract year 2023 version of this HPMS memorandum titled, ''Contract Year 2023 Translated Model Materials Requirements and Language Data Analysis'' on September 23, 2022. This memorandum can be retrieved at: *https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-wk-4-september-19-23.*

[98] CMS Office of Hearings and Inquiries, ''Frequently Asked Questions Regarding Accessible Communications for Individuals with Disabilities, Pursuant to Section 504 of the Rehabilitation Act of 1973 (Section 504) and Section 1557 of the Affordable Care Act (Section 1557), August 30, 2017. Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3.*

[99] Refer to *https://data.census.gov/cedsci/table?q=language&tid=ACSST1Y2019.S1603.*

effectively.[100] The U.S. Census Bureau's 2019 American Community Survey 1 year estimate also finds that 2.3 percent of the population is blind or low vision and 3.6 percent are deaf or have hearing loss, with 13.7 percent of adults over 65 reporting hearing loss or deafness, and 6 percent of adults over age 65 reporting blindness or low-vision.[101] Communication and language barriers are associated with decreased quality of care and poorer health outcomes. In addition, individuals with limited English proficiency are less likely to have routine health visits, more likely to defer needed health care, and more likely to leave the hospital against medical advice.[102] Effective communication is critical to providing high-quality care. Reliance on unqualified individuals to interpret medical information can lead to misunderstandings, poor outcomes, or even death.[103]

We believe that it is a substantial burden for enrollees to have to request each material in an alternate language or request auxiliary aids and services for each material and that requiring enrollees to do so could impede access to care. It is also possible that enrollees may require both auxiliary aids and services for materials and an alternate language (for example Spanish braille). In addition, to ensure the ICPs are developed in consultation with the enrollee as required at § 422.101(f)(1)(ii), it is important that ICP materials be provided in the enrollee's preferred language and, where appropriate, in an accessible format using auxiliary aids and services. Studies consistently show the negative health outcomes that patients with limited English proficiency experience due to the barriers they encounter when interacting with their doctors and care team members, accessing interpreters, and addressing insurance concerns. These outcomes are further exacerbated by vulnerable patients often not knowing their right to have qualified interpreters and other language access provisions at no extra cost.[104] We have become attuned to this issue through our work with Medicare-Medicaid Plans (MMPs). In 2019, CMS conducted a review of MMPs to learn how they capture, record, and use enrollees' language preferences and any need for auxiliary aids and services. We found that MMPs use multiple enrollee touch points to capture this information, including welcome calls, health risk assessments, nurse advice lines, and other interactions associated with member services, enrollment, prescription services, appeals and grievances, and care management. To collect and store this information, MMPs have taken steps such as establishing centralized email accounts within their organizations to capture all translation and auxiliary aid and service requests they receive and to ensure greater consistency and completion of requests, developing database reports that list their enrollees and any identified language or auxiliary aid or service preferences, and storing the information in their eligibility system.

As a result, we believe that there are many ways for MA organizations and Part D sponsors to learn of an enrollee's need for auxiliary aids and services and language preferences and maintain this information. The CMS Guide to Developing a Language Access Plan can provide MA organizations and Part D sponsors with helpful information to ensure that persons with limited English proficiency have meaningful access to services.[105] In addition, the Improving Communication Access for Individuals Who are Blind or Have Low Vision brochure can similarly assist organizations in developing policies to better serve these individuals.[106] We encourage plans to educate enrollees on the availability of translated materials and accessible formats using auxiliary aids and services through such avenues as enrollee newsletters, advertising, or other educational forums. MA plans may use a reward program, as permitted under § 422.134, to provide rewards as a means to encourage enrollees to provide information regarding their need for an alternate language or auxiliary aids and services; in our view, providing this information to the MA plan promotes improved health and the efficient use of healthcare resources (as required by § 422.134 for reward programs) as it ensures that materials and information are adequately furnished to be understood and used by the enrollee in understanding and accessing covered benefits.

We would like to minimize barriers to enrollees receiving materials in alternate languages and accessible formats using auxiliary aids and services and remove any ambiguity associated with MA and Part D plan responsibilities for providing materials in alternate languages and accessible formats using auxiliary aids or services and for SNPs to provide ICPs in alternate languages and accessible formats using auxiliary aids and services. Therefore, we propose to re-designate the paragraphs at §§ 422.2267(a)(3) and 423.2267(a)(3) as §§ 422.2267(a)(5) and 423.2267(a)(5) and add new paragraphs at §§ 422.2267(a)(3) and 423.2267(a)(3) to require MA organizations and Part D sponsors to provide materials to enrollees on a *standing basis* in any non-English languages that is the primary language of at least 5 percent of the individuals in a plan benefit package service area as defined under §§ 422.2267(a)(2), 423.2267(a)(2) and proposed §§ 422.2267(a)(4) and 423.2267(a)(4), which are is discussed later in this section, and in any accessible formats using auxiliary aids and services upon receiving a request for the materials in another language or using auxiliary aids and services or otherwise learning of the enrollee's preferred language or need for an accessible format using auxiliary aids and services. This means that once a plan learns of an enrollee's preferred language and/or need for auxiliary aids and services—whether through an enrollee requesting a material in a preferred language or using auxiliary aids and services, during a health risk assessment, or another touch point—the plan must provide required materials in that language and/or accessible format using auxiliary aids and services as long as the enrollee remains enrolled in the plan or until the enrollee requests that the plan provide required materials in a different manner. We have also proposed language at §§ 422.2267(a)(3) and 423.2267(a)(3) to extend this requirement to the individualized plans of care described in § 422.101(f)(1)(ii) for SNP enrollees. The proposed requirement would allow enrollees to avoid having to submit a request to receive required materials in a preferred language and/or using auxiliary aids and services each time the MA or Part D plan distributes a required material. We note that plans are responsible for providing materials in both a preferred format and using auxiliary aids and services when needed (for example Spanish braille). These modifications at §§ 422.2267 and 423.2267 and other

[100] Refer to *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.*

[101] Refer to *https://data.census.gov/cedsci/table?q=https%3A%2F%2Fdata.census.gov%2Fcedsci%2Ftable%3Fq%3DS1810%26tid%3DACSST1Y2019.S1810%26hidePreview%3Dfalse&tid=ACSST1Y2019.S1810.*

[102] Refer to *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.24.2.435.*

[103] Refer to *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.*

[104] Refer to *https://www.healthaffairs.org/do/10.1377/forefront.20200724.76821/full/.*

[105] Refer to *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.*

[106] Refer to *https://www.cms.gov/files/document/omh-visual-sensory-disabilities-brochure-508c.pdf.*

requirements at Parts 422 and 423 regarding translation obligations and auxiliary aids are in addition to plan obligations under 45 CFR part 92 that govern meaningful access for individuals with limited English proficiency and effective communication for individuals with disabilities. MA and Part D plans must comply with both the rules at § 422.2267 and § 423.2267 and the non-discrimination requirements in 45 CFR part 92. Where one set of regulations imposes a higher or different standard but it is not impossible for the plan to comply with both, the plan must comply with both. Because cost plans, per § 417.428, are subject to the regulations in part 422, subpart V, these requirements also apply to cost plans.

There are no information collections related to creating a standing request for translated materials or materials using auxiliary aids and services. We believe the burden associated with these proposed requirements is exempt from the requirements of PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We believe most cost plans, MA organizations, and Part D sponsors have translators on staff or access them via contractors because of existing translation and auxiliary aid requirements.

2. Require FIDE SNPs, HIDE SNPs, and Applicable Integrated Plans To Translate Materials Into the Medicare Translation Standard Plus Additional Medicaid Languages

Over 1.8 million individuals dually eligible for the Medicare and Medicaid programs speak a language other than English at home or do not speak English fluently.[107] In addition, dual eligibility is a strong predictor of poorer outcomes in an array of Medicare programs,[108] and dually eligible beneficiaries are far more likely than other Medicare beneficiaries to be from racial or ethnic minority groups (48 percent vs. 22 percent). Many dually eligible beneficiaries have low health literacy yet need to navigate a more complex system of coverage than non-dually eligible beneficiaries.

Per the definition of specialized MA plans for special needs individuals in § 422.2, all SNPs must be MA–PDs that comply with both Part 422 and Part 423 requirements. Sections 422.2267(a)(2) and 423.2267(a)(2) require dual eligible special needs plans (D–SNPs), like all other MA–PD plans, to translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. We propose to amend §§ 422.2267 and 423.2267 with a new paragraph (a)(4) that requires that FIDE SNPs and HIDE SNPs, as defined at § 422.2, and applicable integrated plans (AIPs), as defined at § 422.561, translate all Medicare materials listed in §§ 422.2267(e) and 423.2267(e) into any languages required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard at § 422.2267(a)(2). Generally, we expect that the Medicaid translation requirements would be the regulatory standard at § 438.10; however, a State may impose a higher or more stringent translation requirement on its Medicaid managed care plans than is required by § 438.10, so we believe referring to the capitated Medicaid managed care contract rather than § 438.10 is appropriate for this proposed new requirement. Specifically, § 438.10(d)(3) requires that entities make written materials that are critical to obtaining services available in the prevalent non-English languages in the service area. Section 438.10(a) defines prevalent as a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient. Section 438.10(d)(1) requires that the State establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. Under the definitions for FIDE SNP, HIDE SNP, and AIP, each of these types of plan has a companion or affiliated Medicaid managed care plan, which would itself be subject to § 438.10 and the applicable State's translation requirements for Medicaid materials described in § 438.10. We propose to extend the translation standards applicable to the Medicaid materials used by FIDE SNPs, HIDE SNPs, and AIPs to the Medicare materials used by those plans to ensure that the dually eligible enrollees in all FIDE SNPs, HIDE SNPs, and AIPs receive all of the materials necessary for accessing and understanding all of their benefits (both Medicare and Medicaid) in a language that the enrollees understand.

For example, if current §§ 422.2267 and 423.2267 only require translation into Spanish for Medicare materials but the State Medicaid agency requires translation into Chinese as well as English and Spanish, then our proposed revisions to §§ 422.2267 and 423.2267 would also require that the affected FIDE SNP, HIDE SNP, or AIP translate the Medicare materials listed in §§ 422.2267(e) and 423.2267(e) into Chinese as well as Spanish.

These modifications at §§ 422.2267 and 423.2267 do not create exceptions to other laws that govern translation of written materials provided to enrollees that we have previously described. Rather, our intent is to make it easier for dually eligible beneficiaries who are enrolled in FIDE SNPs, HIDE SNPs, or AIPs to understand the full scope of Medicare and Medicaid benefits available through such D–SNPs, which would increase their ability to make informed health care decisions. It would also reduce the likelihood of an enrollee receiving materials in different languages (for example, some in English and some in Spanish) depending on whether the materials are governed by Medicare or Medicaid requirements.

We are considering applying the proposed new requirement to additional or different groups of D–SNPs, such as limiting the proposal to AIPs or to organizations with D–SNP-only contracts as described under § 422.107(e), or expanding the requirement to all D–SNPs and D–SNP look-alikes (that is, the MA plans that meet the standards in § 422.514(d)) during a period before the D–SNP look-alike plan is nonrenewed or terminated. We decided to focus our proposal on all FIDE SNPs and HIDE SNPs, as defined at § 422.2, and AIPs, as defined at § 422.561, because these plans have capitated contracts with State Medicaid agencies and must already translate Medicaid materials to comply with their Medicaid managed care contracts, and would likely either have staff that are capable of translating materials into these languages or contract with organizations to perform these translations. In addition, an increasing number of dual eligible individuals are in FIDE SNPs, HIDE SNPs, and AIPs where the same organization provides coverage of both the Medicare and Medicaid services for the enrollee.

We understand that our proposal would require some FIDE SNPs, HIDE SNPs, and AIPs to translate the Medicare materials listed in §§ 422.2267(e) and 423.2267(e) into additional languages. We believe that the benefit gained by the ability for more enrollees to receive all materials in

[107] Refer to *https://www.resourcesforintegratedcare.com/language_preferences/*.

[108] Refer to *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

their preferred language outweighs this burden. As described previously in this section, these enrollees are far more likely than other Medicare beneficiaries to be from racial or ethnic minority groups or have low health literacy yet need to navigate a more complex system of coverage than non-dually eligible beneficiaries. As a result, to ensure health equity for this population we have proposed including a broad range of D–SNP types but are excluding those D–SNPs that only coordinate with Medicaid services. We welcome comments on our proposal and these potential alternatives we are considering.

3. Exclude Member ID Cards From New Paragraphs Proposed at §§ 422.2267(a)(3) and (a)(4) and §§ 423.2267(a)(3) and (a)(4)

In addition to the proposals described earlier in this section, §§ 422.2267(e)(30)(vi) and 423.2267(e)(30)(vi) currently exclude the member ID card from the translation requirement under §§ 422.2267(a)(2) and 423.2267(a)(2). We propose to amend the member ID card provision at §§ 422.2267(e)(30)(vi) and 423.2267(e)(30)(vi) to expand the exclusion for member ID cards to include the new paragraphs proposed in this section, §§ 422.2267(a)(3) and (a)(4) and §§ 423.2267(a)(3) and (a)(4), respectively.

P. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

We are proposing a number of changes to Subpart V of both 422 and 423 regulations. These changes include requiring third parties to submit marketing materials, notifying enrollees annually that they can opt out of plan business calls; limiting the ability of plans and agents to contact prospective enrollees beyond six months from the time they submit a Scope of Appointment (SOA) or Business Reply Card (BRC); requiring website provider directories be searchable by all required elements (for example, name, phone number, address); adding ''effect on current coverage'' to the Pre-enrollment Checklist (PECL), as well as requiring agents to discuss the PECL during an enrollment call; requiring plans to list benefits at the beginning of the Summary of Benefits and in a specified order; labeling the non-renewal notice as standardized rather than a model, consistent with CMS's guidance instructions; limiting the requirement to record calls between third-party marketing organizations (TPMOs) and beneficiaries to marketing (sales) and enrollment calls; clarifying that the prohibition on door-to-door contact without a prior appointment still applies after collection of a BRC or SOA; prohibiting marketing of benefits in a service area where those benefits are not available; prohibiting the marketing based on information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, costs that dually eligible beneficiaries are not responsible to pay, or other unrealized costs of a Medicare beneficiary; requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they sell; requiring MA organizations and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS; modifying the TPMO disclaimer to add State Health Insurance Programs (SHIPs) as an option for beneficiaries to obtain additional help; placing discrete limits on the use of the Medicare name, logo, and Medicare card; prohibiting the use of superlatives (for example, words like ''best'' or ''most'') in marketing unless the material provides documentation to support the statement, and the documentation is for the current or prior year; and clarifying the requirement to record calls between TPMOs and beneficiaries such that it is clear that the requirement includes virtual connections such as Zoom and Facetime.

Sections 1851(h), 1851(j), and 1852(c) of the Act, which address Medicare Part C, provide CMS the authority to review marketing materials, develop marketing standards, and ensure that marketing materials are accurate and not misleading. These provisions also provide CMS with the authority to prohibit certain marketing activities. Section 1856(b)(1) of the Act provides CMS the authority to add additional standards to the MA program that the Secretary determines are necessary for CMS to carry out the program. In addition, sections 1876(i)(3)(D), 1857(e)(1) and 1860D–12(b)(3)(D) of the Act provide CMS the authority to adopt additional contract terms for cost plans, MA plans, and Part D plans when necessary and appropriate. Likewise, 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) of the Act for approval of marketing materials and application forms for Part D plan sponsors. Section 1860D–4(l) of the Act applies certain prohibitions under section 1851(h) of the Act to Part D sponsors in the same manner as such provisions apply to MA organizations. In addition, under section 1852(c) and 1860D–4(a) of the Act, CMS can require organizations to provide certain materials to Medicare beneficiaries concerning MA and Part D plan choices. These statutory provisions help ensure Medicare beneficiaries are informed and protected when making an election to enroll in an MA (including MAPD) or Part D plan. We believe the changes proposed in this regulation strengthen CMS' ability to ensure MA and Part D marketing to beneficiaries is not misleading, inaccurate, or confusing. Additionally, under 42 CFR 417.428, most marketing requirements in subpart V of part 422 apply to section 1876 cost plans as well. (87 FR 1899).

In accordance with regulations at §§ 422.2261(a) and 423.2261(a), MA organizations and Part D Sponsors (MA organizations/Part D Sponsors) must submit all marketing materials, all election forms, and certain designated communications materials for CMS review. Sections 422.2261(a)(3) and 423.2261(a)(3) prohibit third-party and downstream entities from submitting materials directly to CMS, unless specified by CMS. Following an operational change in May 2021, CMS began permitting TPMOs to submit certain marketing materials. In cases where a TPMO document only markets one MA organization/Part D sponsor, there would be no change for the TPMO, meaning they would still send the document in through the MA organization/Part D sponsor who would submit it into HPMS. For TPMOs that develop materials for more than one MA organization/Part D sponsor, the TPMO would submit the material directly to CMS. Based on CMS' operational change we are proposing to require TPMOs, as defined at §§ 422.2260 and 423.2260, to submit their marketing materials developed for multiple MA organizations and Part D sponsors (and their specific plans) to CMS through HPMS. Specifically, we are proposing to remove §§ 422.2261(a)(3) and 423.2261(a)(3), which as implemented prohibited TPMOs from submitting materials the TPMO alone developed, and modifying §§ 422.2261(a)(2) and 423.2261(a)(2) to require that where marketing materials have been developed by a TPMO for multiple plans, the TPMO must submit those materials that the TPMO has designed and developed to CMS, and such submission may only occur after the TPMO receives the prior approval of each of the MA organizations or Part D sponsors on whose behalf the materials

were designed and developed by the TPMO.

The HPMS is CMS' system of record for marketing materials. In the January 19, 2021 final rule, we modified §§ 422.2261(a)(3) and 423.2261(a)(3) to provide CMS the flexibility to allow third parties to submit materials directly to CMS in the future (86 FR 5998). CMS made this modification in anticipation of changes to HPMS. CMS released an updated marketing module in HPMS in May of 2021. Prior to this release, third-party materials were submitted into HPMS, but the TPMO was required to send materials to an MA organization or Part D sponsor and have the MA organization or Part D sponsor submit the materials on the TPMO's behalf. System changes in 2021 permitted third parties and downstream entities, such as TPMOs, to submit materials directly to CMS following the receipt of prior approval from at least one MA organization or Part D sponsor. The January 19, 2021 final rule enabled the agency to allow submission by third parties and downstream entities because of the timing and uncertainty of the revamped HPMS marketing module.

Since issuing the January 19, 2021 final rule, we have modified HPMS so that TPMOs may submit materials that are being used for multiple MA organizations, Part D sponsors, or plans. We are now proposing to require, rather than permit, TPMOs submit to CMS any material that the TPMO develops for multiple MA organizations and Part D sponsors that meets the definition of marketing and that TPMOs receive prior approval, by each MA organization or Part D sponsor, of the material being submitted on behalf of each of the MA organization or Part D sponsor. Failing to require submission may result in these materials not being subject to CMS review. Thus, we are proposing to remove §§ 422.2261(a)(3) and 423.2261(a)(3) and modify §§ 422.2261(a)(2) and 423.2261(a)(2) to add that TPMOs must submit their materials designed on behalf of and with prior approval from the applicable MA organizations or Part D sponsors.

CMS is proposing to add a new (xix) to § 422.2262(a)(1) and a new (xviii) to § 423.2262(a)(1) to address the use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card. CMS is aware of concerns from external stakeholders about marketing activities and documents that appear to be from Medicare, CMS, or the Federal Government. Through beneficiary complaints and CMS surveillance activities, over the years, we have seen the word ''Medicare'' in names of store fronts (that is, The Medicare Store), on notices or postcards where ''Medicare'' is in large font while disclaimers are miniscule, and in television advertisements where a beneficiary could think that the advertising is coming from CMS. We have also seen logos, which are very similar to the Health and Human Services (HHS) logo on websites and print materials. These logos have featured circles with writing around the circle and a bird, wings or other images that appear to be the same image used by the Federal Government. In addition to the store front, postcards, and television advertisements, there are also numerous third-party internet sites with ''Medicare'' in the URL or a logo similar to the HHS logo, potentially causing a beneficiary to click on a private site when they intend to go to *Medicare.gov* or are seeking official Medicare information or access. Often, it appears as if the materials urging the beneficiary to ''take action'' are from Medicare or that these third parties represent Medicare or the Federal Government. With the increase of third parties in the marketplace, based on CMS' surveillance and complaints received, especially through 1–800–MEDICARE, we are concerned that an increasing number of beneficiaries are being misled into believing the entity they are contacting is Medicare or the Federal Government. One specific example, provided by a Medicare beneficiary, is a postcard with the beneficiary-named address with ''Medicare Notice'' in large, bold letters at the top along with ''Personal & Confidential'' and ''Important Medicare Information.'' This postcard also had a ''Medicare Information'' box listing a ''Customer ID'', formatted to look like an official Medicare beneficiary number. This misleading postcard appeared to be an official document disseminated by the Federal Government. In our review of complaints received through 1–800–MEDICARE, CMS discovered other examples of beneficiaries who mistakenly believed they were calling Medicare rather than a private MA or Part D plan or its agent or broker, likely based on the receipt of a flyer using the word ''Medicare'' in a way that conveyed to the beneficiary that they must call the telephone number on the mailer. These complaints illustrate that the use of the Medicare name is at times confusing and misleading to Medicare beneficiaries.

A top CMS priority, consistent with sections 1851(h)(2) and 1860D–01(b)(1)(B)(vi) of the Act and CMS's implementing regulations at §§ 422.2262 and 423.2262, is to ensure that MA organizations and Part D sponsors disseminate information to beneficiaries that is accurate and not misleading. We are therefore concerned that the use of the term ''Medicare'' in situations like those described above erroneously leads beneficiaries to believe that Medicare-related communications or advertising are disseminated or endorsed by Medicare or the Federal Government, when in actuality such communications are being disseminated by the MA organizations/Part D sponsors themselves, or by entities operating on behalf of the MA organizations or Part D sponsors. Although the types of plan communications described above that feature the word ''Medicare'' typically include disclaimers that state the information presented is not connected to or endorsed by the Federal Government or the Medicare program, these disclaimers are often tiny, difficult to read, and are mixed in with other CMS required disclaimers as well as plan-developed, non-required, disclaimers. While CMS already prohibits inaccurate or misleading information under §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), we believe it is important to specifically prohibit the misleading use of the Medicare name, CMS logo, and products or information issued by the Federal Government (including the Medicare card) in §§ 422.2262(a)(1) and 423.2262(a)(1). We are not including the Medicare Part D mark, as CMS gives Part D sponsors contractual permission to use the mark. By adding a new (xix) and (xviii) we are firmly and clearly prohibiting the improper use of these terms and logos. Therefore, we propose adding a new paragraph (xix) to § 422.2262(a)(1) and a new (xviii) to § 423.2262(a)(1) which specifically prohibits the use of the Medicare name, CMS logo, or official products, including the Medicare card, in a misleading manner.

Since CMS contracts with MA organizations and Part D sponsors, CMS holds these organizations accountable for the actions of their first tier, downstream and related entities, per §§ 422.504(i) and 423.505(i). If CMS determines that the Medicare name, CMS logo, or official products like the Medicare card, have been used in a misleading manner by a first tier, downstream or related entity (FDR), CMS would address the issue with the MA organization or Part D sponsor on whose behalf the FDR was operating and hold the sponsoring organization accountable for the misleading information.

In our January 2021 final rule, we prohibited plan use of unsubstantiated statements except those used in taglines

and logos in 42 CFR 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii). Prior to the January 2021 final rule, we had prohibited the use of unsubstantiated superlatives and pejoratives, except when used in logos and taglines, through our Medicare Communications and Marketing Guidance. We now propose to further restrict the use of superlatives by prohibiting all superlatives unless substantiating supporting data is also provided with the material and essentially adopt a regulation that builds upon our prior guidance. We are proposing this for all superlatives, including those used in logos and taglines. Previously, CMS generally required plans to provide substantiating data to support the use of a superlative. However, that substantiating information was only provided to CMS, resulting in the beneficiary seeing the superlative without no context. Currently, the beneficiary has no knowledge of how the superlative is determined, potentially misleading the beneficiary to believe a statement which may be partially or mostly true, but lacking context and important specificity. For example, an MA plan may advertise that it has the *largest* network, which on a national basis may be accurate. However, when looking at a particular service area, this MA plan may have the smallest network. Permitting the use of superlatives without specific information explaining the basis or context, is potentially misleading to beneficiaries so we have reconsidered the scope of §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) as previously finalized.

CMS believes it is critical to provide either actual data or information, such as reports or studies, that forms the basis for a superlative statement in order for beneficiaries to review and understand the context and reference point for the superlative. This documentation and/or data can be referenced through footnotes explaining the basis, noting the source, with enough information for a beneficiary to locate, or providing the actual comparison done to determine the superlative. For example, if a plan stated that they have the lowest premiums, the plan would need to state their premium and the premiums of other plans in the service area, or reference a study, review or other documentation that supports the superlative and with which the beneficiary can make accurate comparisons between plans.

We are also proposing to add a requirement that the supportive documentation and/or data be based on current data. Our proposed regulation text requires that the supportive documentation or data must reflect data, reports, studies, or other documentation to have been published either in the existing contract year or the prior contract year. For example, a health plan could not make the statement in CY 2022 that they have the largest provider network in an area using 2018 data. Rather, in CY 2022, the statement that a health plan has the largest network in an area must be supported by documentation and/or data published as of January 1, 2021 or later. Data and the underlying situations can be dynamic and change over time, therefore, CMS is proposing that recent data, meaning the current or the prior contract year data, are the only data that may be used to substantiate superlatives. We believe any data older than the prior contract year may be misleading, given the age of the data and the potential of the data to have changed. Based on this, we propose to modify paragraphs §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) to prohibit the use of superlatives, unless sources of documentation and/or data supportive of the superlative is also referenced in the material and to provide that such supportive documentation and/or data must reflect data, reports, studies, or other documentation that has been published in either the current contract year or prior contract year.

In §§ 422.2263(b) and 423.2263(b) we propose adding a new (8) which prohibits organizations from advertising benefits not available in a service area, unless doing so is unavoidable in a local market. This prohibition is codifying our previous guidance, as previously outlined in section 30.1 of the 2016 Medicare Marketing Guidelines (MMG),[109] providing that marketing activities should be limited to a plan's service area unless doing so was unavoidable, such as advertising in a local newspaper that may be distributed outside a service area. In cases where marketing outside a service area was unavoidable, CMS's guidance provided that the plan's service area be disclosed.

Over the past few years, CMS has seen a significant increase in national marketing which promotes benefits such as dental, vision, and money back on a beneficiary's Social Security check. While many of these benefits are available to a large number of beneficiaries, they are not available in all service areas or to all Medicare beneficiaries in the amounts often advertised. For example, in 2021 there were national advertisements that claimed a beneficiary ''could get up to $144 back'' on their Social Security check, which would be accomplished through a reduction in the beneficiary's Medicare Part B premium. A premium reduction of this magnitude would have covered most of the standard 2021 Part B premium of $148.50. However, the number of counties or states where one or more available plans offered the advertised Part B premium reduction of $144 was small. In fact, for CY 2021, Florida and Puerto Rico were the only states or territories that had plans with a reduction of $140 or more, and in CY 2022 the only states or territories that had plans with a reduction of $140 or more were California, Florida and Puerto Rico. Further, although there were plans available in these states, the plans offering the $140 or more buy down were not available in all counties. Since beneficiaries in more than 60% of states only have access to plans that offer a Part B premium reduction of $99.00 or less (CY 2022), advertising on a national or even regional level that a beneficiary can get up to the full amount or even close to the full amount is potentially misleading. And although over 30% of states and territories offer Part B premium reduction of $100 or more, this reduction is not available in all counties in each State and territory. These national advertisements publicize that a beneficiary can get up to a certain dollar amount (for example, $144) even if there are no plans available in that state that offer $144 or any dollar amount close to $144. CMS believes that if a plan offering ''up to'' the top dollar amount is advertised as available for enrollment, then such a plan offering that top dollar amount should be available to beneficiaries who are receiving or exposed to the advertisement where they reside; otherwise we believe it is potentially misleading to potential enrollees. A beneficiary calling, based on an advertisement touting up to $144 back, would expect that plans would be available that would provide a reasonable Part B premium reduction. However, the actual reduction may be minimal, anywhere from $1 to $25, significantly far from the ''up to'' advertised amount; or in other cases, there may not even be a Part B premium reduction in that particular service area. We believe this practice—touting a reduction far greater than what is available has the effect of getting beneficiaries to contact the company, hoping for financial assistance, only to be told there is little to no Part B

[109] *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2016-Medicare-Marketing-Guidelines-Updated.pdf.*

premium reduction—is a misleading tactic that is more likely designed to attract a beneficiary's attention so that the beneficiary will call the number and then, be subject to additional marketing and potentially switched to a plan not that is not well suited to meet the beneficiary's health care needs.

A similar issue exists for other MA benefits such as dental, vision, and hearing as well as Part D benefits, non-formulary medications and over-the-counter medications. There have been national advertisements that promote plans with high benefit amounts for certain benefits (for example, up to $2,500 in dental benefits). CMS believes advertising up to a $2,500 dental benefit on a national level is misleading when some markets may not even have access to a plan with dental or others only have access to a plan with limited dental (for example, $500). While many beneficiaries have access to MA plans with some level of additional dental, vision and hearing benefits, advertising benefits up to a large dollar amount (for example, $2,500) is misleading when the MA plan options available to a beneficiary provide a significantly lower value benefit (for example, $500).

CMS has seen advertisements which market up to $144 dollars back on the beneficiaries' Social Security check, or thousands of dollars in hearing, dental and vision, to entice a beneficiary to call the 1–800 number possibly believing they can receive the maximum amount of benefits advertised. CMS has listened to recorded calls between a beneficiary and an agent in which the beneficiary starts off by asking about how to get $144 back in their Social Security check. Based on its review of recorded calls,[110] CMS has learned that once the beneficiary places a call to the advertised number, the agent may market a plan that does not provide a Part B premium reduction at all or that offers a premium reduction at a much lower level than the advertised dollar value, or a plan with more limited dental, hearing or vision than was advertised. Once the agent or broker has the beneficiary on the line, the beneficiary is either put in a position of trying to end the call or listening to an agent sell a plan in which the beneficiary was not interested, potentially leading the beneficiary into enrolling in a plan that does not offer the advertised benefits. Because of the initial call, which was based on unavailable benefits, the beneficiary may end up enrolling in a plan that does not best meet the health care needs of the beneficiary. In this situation, the beneficiary may have benefited by staying in their existing plan, and may even have stayed enrolled in their existing plan, if not for the advertisement urging the beneficiary to call to ''get the money they deserve.''

As mentioned above, when a plan advertises benefits which are not available to beneficiaries in the service area where the advertisement airs, that type of marketing is misleading. We believe that beneficiaries should only receive marketing that advertises benefits actually available to the beneficiary where the beneficiary resides (that is, in a service area that covers where the advertisements air). Therefore, we are proposing a new (8) at §§ 422.2263(b) and 423.2263(b) that provides that MA organizations and Part D sponsors may not engage in marketing that advertises benefits that are not available to beneficiaries in the service area where the marketing appears unless unavoidable in a local market.

We are also proposing a new (9) at §§ 422.2263(b) and 423.2263(b) that prohibits marketing unless the names of the MA organizations or Part D sponsors that offer the benefits are being advertised are clearly identified. In cases where the MA organization or Part D sponsor uses a specific marketing name, as identified in HPMS, that marketing name can be used in place of the MA organization or Part D sponsor name. CMS has seen an increase in the marketing of benefits, through television, websites, and mailers that mention additional benefits such as dental, vision, hearing, as well as low or zero-dollar premiums. These advertisements do not identify which product(s), plan(s), or specific plan(s) benefits are being advertised, but rather act as a lead generator to obtain beneficiary contact information. When a beneficiary calls, returns a flyer, or clicks on a link on a web page, the advertising entity (which may be either an MA organization, a Part D sponsor, or a TPMO) may be able to obtain a beneficiary's contact information, which is then used by that entity for unlimited future calls or for providing that information to other entities that then contact the beneficiary. One particular internet site [111] requires an individual to enter their name, email address, and phone number prior to looking at any plan information. The disclaimer at the bottom of the ad (and often in much smaller font) states ''By entering my contact information and clicking ''Next'' above, I consent to receive emails, telephone calls, text messages and artificial or pre-recorded messages from. . .licensed insurance agents or their affiliates and third-party partners, regarding health insurance products and services including Medicare Advantage Plans and/or Prescription Drug Plans, at the email address and telephone number provided above, including my wireless number (if provided), using an automated telephone dialing system.'' By ''automated telephone dialing system,'' the language seems to be referring to what are commonly referred to as robo-calls. In order for the beneficiary to get any information, they are forced to agree to be contacted not just once based on the initial inquiry, but for unlimited calls, texts, and emails from the internet site they visited, as well as any other company to whom the internet site gave or sold the beneficiary's information. We do not believe beneficiaries realize or want their contact information to be provided to other entities just because the beneficiary wanted to get information about available plans from one internet site. We believe that many of the unsolicited contact complaints that CMS has received (through 1–800–MEDICARE, online complaint system, anecdotally from stakeholders, etc.) are the result of a beneficiary inadvertently or unknowingly agreeing to having their personal information provided or sold to others entities, who then call the beneficiary and market MA products.

CMS believes there are specific, important reasons for advertisements to contain MA organization and Part D sponsor names. First of all, we believe including the names in the advertisement will help the beneficiary understand that they are calling a plan or a plan representative and not Medicare, the government, or a non-partisan entity. Adding the names provides information to put the beneficiary in control of whether they even want to contact the agent because by having the name on an advertisement, the beneficiary can research the MA organization or Part D sponsor, including their Star Ratings and complaints, or discuss the plan with relatives or friends whom they trust to help make health care decisions. The beneficiary can then make a more informed decision on whether they want to contact the agent to learn about that particular plan. Without knowing the plan name, the beneficiary may find themselves in a position of listening to an agent (especially if that agent is in

[110] CMS has retained the recordings of these calls. The calls include sensitive information, and as such, we feel it would be inappropriate and illegal to include them as part of this public record.

[111] HPMS is the system of record for storing marketing websites submitted to CMS for review and approval.

the beneficiary's home) market a plan that the beneficiary is not interested in joining.

Not only does this proposed policy assist beneficiaries, it will also assist CMS and MA organizations and Part D sponsors to ensure the marketing reflects the appropriate MA organizations and Part D sponsors. CMS is proposing to require TPMO-developed marketing to be submitted into HPMS and currently permits TPMOs to submit marketing materials into HPMS. Under our proposal, once submitted, each MA organization or Part D sponsor would decide whether they want the TPMO to use that marketing piece on their behalf. If an MA organization or Part D sponsor ''opts into'' the piece, the TPMO may then use it on their behalf and marketing those organizations. If the MA organization or Part D sponsor ''opts out'' of the marketing piece, then the TPMO would not have permission to market *those specific organizations.* By requiring MA organization and Part D sponsor names both CMS and the organization would then be able to ensure that only those MA organizations and Part D sponsors who opted into the TPMO using the piece are being advertised in that piece. And if CMS determines a piece is misleading, we will then be able to identify the organizations from the advertisement, compare them to the ones that opted in and address the issue with those organizations who opted into the TPMO piece. This will allow CMS to quickly notify the MA organization or Part D sponsor of the issues, have the organization resolve the issues, and get the misleading materials out of circulation quickly.

Therefore, we are proposing a new (9) at § 422.2263(b) to prohibit MA organizations from marketing any products or plans, benefits, or costs, unless the MA organization or marketing name(s) (as listed in HPMS of the entities offering the referenced products or plans) are identified in the marketing material. We are also proposing a new (9) at § 423.2263(b) to prohibit Part D sponsors from marketing any products or plans, benefits, or costs, unless the Part D sponsor or marketing name(s) (as listed in HPMS of the entities offering the referenced products or plans) are identified in the marketing material.

In addition, we propose to set requirements on how the names of the sponsoring organization are displayed or identified in marketing materials. In reviewing television, print, and online marketing, the disclaimers are often small, not displayed long enough, read too fast, or are difficult to find. We propose adding requirements in this new paragraph (9) to ensure the information is visible. We propose adding that print advertisements must have MA organization, Part D sponsor, or marketing names in 12-point font and may not be solely in the disclaimer or fine print. We use the phrase ''fine print'' as it is generally defined to mean printed matter in small type or in an inconspicuous manner. For television, online, or social media-based advertisements, we propose that these names must either be displayed during the entire advertisement in the same font size as displayed benefits and phone numbers, or be read within the advertisement at the same pace as advertised benefits or phone numbers. For radio or other advertisements that are voice-based only, we propose that these names must be read at the same speed as the phone number. To implement these new requirements, we are proposing new paragraphs (b)(9)(A), (B), and (C), respectively.

We are proposing to add a new (10) to §§ 422.2263(b) and 423.2263(b) to address the marketing of ''savings'' for beneficiaries. As part of our marketing surveillance and reviews, CMS has seen advertisements touting that a beneficiary can save $9,000 or more on their prescription drugs, or over $7,000 in health care expenses if they join a particular MA plan or Part D plan. In the example referring to savings for prescription drugs, this advertisement included a small disclaimer stating that the ''savings'' figure is based on the usual and customary price someone without prescription drug insurance would pay. In other examples, MA organizations, Part D sponsors, or TPMOs are marketing dual eligible Special Needs Plans (D–SNPs) that provide ''savings'' of over $7,000. In this situation, the ''savings'' described in the advertisement refers to the Part B Medicare premium and copay amounts that are covered by Medicaid for fully dual-eligible beneficiaries or are the costs saved through the Prescription Drug savings program, which is based on income. However, with both of these examples, most beneficiaries are not saving the advertised amount of money because they would never have incurred many of those out-of-pocket expenses. Specifically, a beneficiary that already has prescription drug coverage (such as a current Part D plan or other creditable prescription coverage from before the individual became eligible for Medicare) would not save $9,000 in out-of-pocket costs by switching to the advertised plan because they already had coverage for their drugs through a different plan. This advertised ''savings'' is only applicable if the beneficiary currently had no drug coverage, meaning they had to pay for all of their drugs out of pocket. Likewise, the above example of advertisements marketing D–SNPs, the advertisements generally have very small, fine print that says the individual may need to be income eligible or Medicare and Medicaid eligible in order to receive the advertised savings. However, since dual eligible beneficiaries already have Medicaid coverage or are already in a dual plan they are not saving the full $7,000 because they never paid the full $7,000 in their old or existing plan. Further, if the beneficiary is eligible to have Medicaid pay certain costs on the beneficiary's behalf (such as payment of Part B premiums) or is protected from paying cost sharing by § 422.504(g)(1)(iii), the advertised savings are not unique to the advertised plan in any way.

We believe that these commercials and other types of advertising (for example, direct mailers) are techniques that TPMOs, MA organizations, and Part D sponsors use to entice a beneficiary into calling a 1–800 number for plan X, mistakenly believing that she or he will save thousands of dollars by switching plans, as identified in the examples above. To address our concerns about beneficiaries being misled, we propose to add a new paragraph (b)(10) at §§ 422.2263 and 423.2263 to prohibit MA organizations and Part D sponsors from including information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

Next, we propose adding a new paragraph (A) to §§ 422.2264(a)(2)(i) and 423.2264(a)(2)(i) to add to the current prohibition of door-to-door solicitation. Business Reply Cards (BRC) and other types of documents where the beneficiary requests additional information are intended to allow the agent to reach out to the beneficiary via telephone, email, or direct mail. One particular agent asked CMS if the BRC gives them the legal right to visit a beneficiary's home unannounced. We do not believe a beneficiary filling out a BRC necessarily indicates a beneficiary's intention give permission for an agent to show up unannounced, at their home, requesting to market MA or Part D plans to that beneficiary. CMS considers this activity to be door-to-door solicitation. Therefore, we propose adding a new (A) to §§ 422.2264(a)(2)(i)

and 423.2264(a)(2)(i) which provides that contacting a beneficiary at his or her home is considered to be door-to-door solicitation unless an appointment at the beneficiary's home at the applicable date and time was previously scheduled.

Currently, regulations at §§ 422.2264(b) and 423.2264(b) permit MA organizations and Part D sponsors to contact existing members, and to a limited extent, former members, as plan business. In §§ 422.2264(b) and 423.2264(b) we define plan business activities to include calling current members to discuss Medicare products. In addition, in §§ 422.2264(b)(2) and 423.2264(b)(2), we currently require that MA organization and Part D sponsors provide beneficiaries an opportunity to opt out of being contacted concerning plan business. However, we have interpreted and implemented this regulation as requiring MA organizations and Part D sponsors to present the opt-out opportunity one time, regardless of how many subsequent contacts an enrollee receives. We are proposing, in §§ 422.2264(b)(2) and 423.2264(b)(2), a change that would require each MA organization and Part D sponsor to provide the opt-out information to all its enrollees, regardless of plan intention to contact, at least annually in writing, instead of just one time. Over time, beneficiaries may realize that having plans contact them regarding marketing is not necessary. Beneficiaries, by only receiving the opt-out option once under current regulations, may fail to realize that they have the option to opt out at any time. By requiring a written annual notification from plans, our proposed new requirement will ensure beneficiaries are reminded that they may decide at any time to opt out of being contacted by their MA organization/Part D Sponsor about plan business.

Therefore, we are proposing MA organizations/Part D Sponsors provide beneficiaries with additional notice, in an annual written communication, about their ability to opt out of being contacted about plan business. We are deferring to plans on how best to communicate this, as we believe that they are in the best position to develop appropriate language based on the plan business they conduct. In addition, we are not proposing the specific written format that plans must utilize when communicating this information during the year, nor specifying when the plan must provide this information during each contract year. MA organizations/Part D sponsors may provide this opt-out notification as a single letter, in a welcome packet, or another method of written communication. The enrollee's decision to opt out of contacts for purposes of plan business will remain in effect until an enrollee chooses to opt in. We solicit comment on whether CMS should expand the existing and proposed notice requirements in some fashion as a way to ensure that Medicare beneficiaries are not marketed MA/Part D plans in a way that is similar enough to cold calling that it should be prohibited.

Our regulations at §§ 422.2264(c) and 423.2264(c) regulate what is permitted at sales and educational events as well as conduct that is prohibited at these events. Currently, MA organizations and Part D sponsors, including agents and brokers, may not market specific MA/Part D plans or benefits at educational events. However, CMS currently permits MA organizations and Part D sponsors participating in educational events to set up future personal marketing appointments and to collect beneficiary contact information including Scope of Appointment forms (SOAs) at educational events. Our regulations also permit marketing events to immediately follow an educational event, provided the beneficiary is made aware of the change and is given an opportunity to leave prior to the beginning of the marketing event.

In 2018, prior to the implementation of §§ 422.2264(c) and 423.2264(c), the MCMG prohibited many of these activities, such as holding marketing events following an educational event, distributing SOA cards, and setting up future individual marketing appointments. Since the January 2021 final rule, CMS' review of marketing to beneficiaries has expanded. We have reviewed complaints about confusing and misleading marketing tactics received through 1–800–MEDICARE and have heard from industry groups concerned about the changes in our policy regarding educational events. Since the 2021 final rule, complaints to CMS have increased alleging unsolicited contact. We believe that some of these complaints may be attributed to the collection (and later use) of contact information or SOA cards at educational events.

We are proposing, in §§ 422.2264(c) and 423.2264(c), to reinstate the prohibition on accepting SOA cards or the collection of beneficiary contact information at educational events. Section 1851(j)(1) of the Act prohibits sales and marketing to take place at educational events. Such events are meant to provide information on how Medicare works including the options of Original Medicare, Medigap plans, Part C, and Part D. These events are aimed at informing beneficiaries on what Medicare covers and the different options a beneficiary has when they are Medicare-eligible or are looking at the options they have to switch the way they receive their Medicare benefits. In other words, these events are meant to provide generic information about the different options, rather than to persuade beneficiaries to enroll in any type of plan (for example, MA–PD or Medigap) or in a plan offered by any specific sponsoring organization.

Although the collection of beneficiary information through SOAs or BRCs was previously permitted, we now believe that collection of contact information at educational events should not be permitted. As mentioned in our May 2022 final rule, the number of marketing complaints has increased significantly over the past few years. Specifically, a significant portion of these complaints involve unsolicited contact. A likely contributor to these contacts is a beneficiary not realizing the contact form provides permission to be called by an agent at some time in the future. CMS has also heard from beneficiary groups requesting that CMS reinstitute the beneficiary protections from the MCMG that were not included in the January 2021 final rule regarding educational events.

The beneficiary attends an educational event to learn about Medicare, unlike a sales event where a beneficiary has decided that they want to look further into a plan to enroll. Collecting contact information at educational events potentially unduly pressures a beneficiary into providing their personal information. Agents passing out SOA cards, possibly watching beneficiaries fill them out, and then collecting these cards can put a beneficiary in an uncomfortable position of having to decide whether they want to oblige or draw attention by declining. This especially may be the case if the beneficiary feels like they should provide this information in exchange for attending the educational event, which could include the provision of a meal and helpful question and answer opportunities in addition to general information. We believe the beneficiary needs to be in charge of and control whether they want to be contacted, by whom, and in what form. Therefore, to ensure such decisions remain with the beneficiary, we propose to amending the regulations that list the activities that are permissible to include in educational events (§§ 422.2264(c)(1)(ii) and 423.2264(c)(1)(ii)) by removing the paragraphs that authorizes obtaining

beneficiary contact information, including Scope of Appointment forms.

The current regulations at §§ 422.2264(c)(1)(ii)(C) and 423.2264(c)(1)(ii)(C) also permit agents to set up future personal marketing appointments at educational events. Similar to SOAs and contact information, we believe that beneficiaries should be in charge of with whom they speak, when they meet with an agent, and what products they want to discuss with that agent. In the case of educational events, the beneficiary generally attends the event to learn about Medicare, not to facilitate a sales meeting where the beneficiary is urged to enroll in a plan. Once an agent speaks with a beneficiary at an educational event, the beneficiary may feel pressured into setting up a marketing appointment. The ''on the spot'' request at an educational event does not provide the beneficiary enough time to consider whether they want an someone to come to their home and market a plan to them for the purpose of enrollment. We believe that an educational event should be solely for education; not lead generation or future marketing opportunities for agents. Therefore, we also propose removing §§ 422.2264(c)(1)(ii)(C) and 423.2264(c)(1)(ii)(C), which currently permit organizations and agents to set up future marketing appointments at educational events.

CMS is also concerned about marketing events directly following an educational event. As stated above, educational events are meant to provide information on how Medicare works, including the options of Original Medicare, Medigap plans, Part C, and Part D, not meant to persuade beneficiaries to enroll in a plan. Beneficiaries attending an educational event directly followed by a marketing event may feel pressured into staying for the marketing event at the conclusion of the educational event. For example, an agent may hold an educational event providing free meals and desserts, which is directly followed by a marketing event. Beneficiaries may feel pressured into staying for the marketing event because of the offer of a free meal at the event that follows the educational event. Although our current regulations require there be an opportunity to leave prior to the sales event, we do not regulate how long that needs to be, nor do we prescribe what the agent can or cannot say regarding the sales event. Beneficiaries may feel obligated to stay for a variety of reasons, including not having enough time to gather their belongings or feeling awkward leaving when others are staying, adding additional pressure to stay and possibly enroll in an MA or Part D plan, especially when they only came to the event to learn about Medicare and the options available to them. Furthermore, attending a marketing event right after an educational event may raise the risk of beneficiaries being confused that the benefits of an MA or Part D plan in general are actually unique to the specific plan options that are being marketed. For example, a factual and impartial statement like, ''It is important to consider your out-of-pocket costs and which drugs you take when deciding on your enrollment options'' in the educational event could be followed up in the marketing event that uses the same phrasing and terms in describing a specific plan's benefits. The beneficiary might conflate these issues if the educational and marketing meetings are held so close in time.

When CMS permitted marketing events to immediately follow educational events, we were concerned about beneficiaries having to go to two separate events at different times, potentially in two different places. Over the past few years, there has been a significant increase in the use of technology. The COVID–19 pandemic resulted in fewer face-to-face communications and more technology-based marketing, such as Zoom calls and live events on the internet. If a beneficiary attends an educational event and wants further information about a specific MA or Part D product, the beneficiary can go to a marketing event or ask for a one-on-one appointment either in person or through communications technology. Although there are still many beneficiaries that may not have significant knowledge about digital technology, we believe the number of beneficiaries that understand the technological options will increase. The use of technology has provided more options for beneficiaries, and with the increase in technology education CMS is proposing, the need for sales events to follow educational events because of travel considerations will become less important.

By separating educational events from the marketing events, beneficiaries are afforded the time to consider all their questions and options. The beneficiary can reach out to the agent if and when they want to hear more about the particular plan the agent is selling. CMS believes this proposal to separate marketing from educational events will alleviate the pressure a beneficiary may feel to stay for a marketing event and will protect beneficiaries from undue pressures to enroll in a plan for which they may not be interested or a plan that does not best meet their health care needs. Based on this, we are proposing to prohibit marketing events from taking place within 12 hours of the educational event in the same location. We are proposing changes to §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) to read, ''Marketing events are prohibited from taking place within 12 (twelve) hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.'' We believe a 12-hour window is important to ensure beneficiaries are not pressured into attending a sales event. This will usually give beneficiaries until the next calendar day, providing sufficient time to think about the impartial and factual information provided at the educational event. We are concerned that a short window, such as 10–15 minutes, will not provide beneficiaries with enough time to finish conversations, pack their belongings, and leave the facility prior to the sales event starting. If a beneficiary is unable to leave during the break, we are concerned that the beneficiary may be ''guided'' to the sales event or pressured into attending by being told the event won't last long or that there will be no pressure to join, or will be made to feel obligated to go to the sales event. CMS believes the best way to protect beneficiaries by being pressured into attendance would be for the sales event to be at a different time, with a sufficient amount of time between the two events. We also believe it is necessary to limit this new requirement to when the sales event is in the same location as the educational event. This ensures that an agent or broker can hold a sales event the same day as an educational event, provided the sales event is in a different location. If an agent wishes to have a sales event three miles from an educational event, we do not want to limit the ability of the agent or broker to do so. Therefore, we are proposing to revise paragraph (c)(2)(1)(1) of §§ 422.2264 and 423.2264 to prohibit marketing events from taking place within 12 hours of an educational event, at the same location.

Sections 1851(j)(2)(A) and 1860D–4(l)(2) of the Act require an advance agreement with a prospective enrollee on the scope of the marketing appointment, which must be documented. Our regulations at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) reiterate this requirement, designating this requirement as a Scope of Appointment. Both the statute and the regulations require an advance agreement between the beneficiary and the agent. Previously, we interpreted

this standard of agreement in advance in our MCMG guidance as meaning as 48 hours prior the appointment when practicable. We propose codifying our previous marketing (MCMG) guidance by prohibiting personal marketing appointments from taking place until after 48 hours have passed since the time the SOA was completed by the beneficiary. However, we are not proposing to include ''when practicable'' in the proposed regulation. We believe ''when practicable'' nullifies the purpose of the 48 hour timeframe, given the many reasons that might be cited for why waiting the full 48 hours is not ''practicable,'' such as the beneficiary living an hour away, the beneficiary wanting to discuss the products immediately following the signing of the SOA, the beneficiary may feel pressured by the agent to discuss the product immediately, or the beneficiary needs to arrange to have the person that helps them with health care decisions available at the meeting. The reasons for why a meeting must occur within the 48 hour timeframe are numerous and subjective, meaning what is practicable for one person may not be practicable for another, thus we are concerned about our ability to enforce the regulation if we include ''when practicable'' in requiring advance agreement at least 48 hours before the meeting. In addition, given today's technology and the fact that we permit SOAs to be completed via telephone, electronically, or in paper form, obtaining a SOA 48 hours prior to the appointment should not present a significant burden for either beneficiaries or the plan representatives and agents that engage in these meetings. Therefore, we are proposing to add ''At least 48 hours'' before the word ''Prior'' to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to read, ''At least 48 hours prior to the personal marketing appointment beginning, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).''

Regulations at §§ 422.2264(c)(3)(iii) and 423.2264(c)(3)(iii) prohibit an MA organization/Part D sponsor, including their agents and brokers and other first tier and downstream entities, from marketing a health care product during a personal marketing appointment beyond the scope agreed upon by the beneficiary. Sections §§ 422.2274(g)(1) and 423.2274(g)(1) require that MA organizations/Part D sponsors ensure TPMOs acting on their behalf adhere to any requirements that apply to the plan itself. Therefore, the requirement for noting the scope of a personal marketing appointment (that is, the SOA) is applicable to TPMOs. Currently, CMS requires permission to be granted and completed, concerning the products that will be discussed, prior to the marketing discussion. The existing regulations do not stipulate a timeframe in which the beneficiary may be contacted after an SOA is completed or an expiration date after which the SOA is invalid.

CMS also is aware that MA organizations, Part D sponsors and TPMOs encourage beneficiaries to fill out business reply cards (BRC) or similar mechanisms so the MA organization/Part D sponsor or TPMO has permission to contact the beneficiary at a later date. BRCs are different from SOAs in that the SOA must have the products to be discussed on the document, while many times the BRC is simply obtaining contact information (that is, name, phone number, address, email). While SOAs are required, BRCs are not required. However, we have the same concerns with BRCs as we do with SOAs, BRCs often are open-ended, allowing an MA organization, Part D sponsor or TPMO to contact a beneficiary at any point in the future. For example, a beneficiary could fill out a BRC in October of 1 year and be contacted by the MA organization/Part D sponsor or TPMO 24 months later, well beyond the timeframe that the beneficiary would reasonably expect to be contacted about their plan choices and decision-making when they filled out the card.

CMS is proposing to modify the current regulations at §§ 422.2264(c)(3)(iii)(A), 422.2264(c)(3)(iii)(B), 423.2264(c)(3)(iii)(A) and 423.2264(c)(3)(iii)(B) to limit the validity of the SOAs and BRCs in §§ 422.2264(c)(3)(iii)(A) and 423.2264(c)(3)(iii)(A), and the SOAs in §§ 422.2264(c)(3)(iii)(B) and 423.2264(c)(3)(iii)(B), to six months from the beneficiary's signature date or the beneficiary's request for more information. BRCs and requests for additional information are not applicable to paragraph (B) because CMS does not have the authority to regulate how long a BRC is valid for non-MA/Part D products. A beneficiary's permission to allow contact by an MA organization/Part D sponsor or a TPMO is not, and should not be, open-ended. Beneficiaries who request information regarding MA organizations/Part D sponsors are requesting information at that present time. Since the purpose of the SOA or BRC is for beneficiaries to discuss plan products applicable for the present or following contract year, having the SOA or BRC expire after 6 months satisfies that purpose, and would prevent agents from using it in perpetuity and thus avoiding the statutory and regulatory prohibitions on unsolicited contact and cold calling. If a beneficiary wants the agent tied to the SOA or BRC to continue contacting them beyond 6 months, the agent may secure and document that permission through a new SOA, BRC, or similar mechanism.

In accordance with § 422.2265(b)(4), MA organizations are required to have a searchable provider directory on their website. The current regulations do not identify the elements by which the provider directory can be searched, leaving that up to each organization. We are proposing to modify § 422.2265(b)(4) by requiring the organization's provider directory be searchable by every element, such as name, location, and specialty, required in CMS' model provider directory. We believe this proposal is necessary to assist beneficiaries in finding particular providers. For example, if an organization only provides a beneficiary with the ability to search by location, the beneficiary would have significant difficulties finding a particular specialty or a particular provider. In section III.A.3. of this proposed rule, we are proposing to add two new requirements to § 422.111(b)(3)(i) that organizations must include providers' cultural and linguistic capabilities and identify certain providers waived to treat patients with MOUD in their provider directories. As adopted and with our proposed revisions, § 422.111(b)(3)(i) requires organizations to include these two new elements in their provider directories, therefore, our proposed modification to § 422.2265(b)(4) would require the organization's provider directory be searchable by these two new elements. By requiring website provider directories be searchable by every element, our proposal would ensure that a beneficiary would be able to locate specific provider specialties, as well as providers by names, addresses, or other elements the organization has listed in the online provider directory. Therefore, we propose to modify § 422.2265(b)(4) to require the directory be searchable by every element.

CMS is also proposing to modify the pre-enrollment checklist (PECL) requirements at §§ 422.2267(e)(4) and 423.2267(e)(4). First, we are proposing to add new paragraphs at §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii), to add ''Effect on current coverage'' to the list of references currently provided within §§ 422.2267(e)(4)(i)–(vii) and 423.2267(e)(4)(i)–(vii). Second, we are

proposing to update §§ 422.2267(e)(4) and 423.2267(e)(4) to require that plans review the PECL with the prospective enrollee during telephonic enrollments.

The PECL contains important information prospective enrollees need to know prior to enrolling in an MA or Part D plan. It ensures beneficiaries understand important documents and what information is in such documents, such as the Evidence of Coverage, which provides all costs, benefits, and plan coverage. The PECL also includes information designed to help beneficiaries, such as a reminder to make sure their doctors, pharmacies, and prescriptions are either in the plan's network or covered in their formulary. Finally, the existing PECL reminds beneficiaries of certain plan rules, formularies, and out-of-network services are not covered except for emergency and urgently needed care, and that benefits and costs may change on January 1 of each year.

In §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii), we propose to add ''Effect on current coverage'' to the list of information that must be referenced as part of the PECL. Over the past 2 years, CMS has been doing an in-depth review of 1–800–MEDICARE complaints. Our reviews revealed numerous beneficiary complaints that they were not aware their current coverage, such as an existing MA plan, a Medigap plan, or their Tri-care plan would end once they enrolled in an MA plan. Thus, CMS is proposing to add effect on current coverage to the list of information that plans must provide to prospective enrollees in the PECL, as we believe it will provide additional education to beneficiaries on the implications of choosing an MA or Part D plan and ensure beneficiaries are fully aware that this selection will cause their existing coverage to end.

In §§ 422.2267(e)(4) and 423.2267(e)(4), we are also proposing that the PECL be reviewed with the prospective enrollee during telephonic enrollments as well as provided when hard-copy enrollment forms are provided. As previously mentioned, the PECL provides information necessary for beneficiaries to understand the details of the plan for which they are enrolling. Although the PECL must be provided with an enrollment form, CMS' review of telephonic enrollments revealed that the neither the PECL nor its substance was being conveyed to beneficiaries during the enrollment process. Specifically, complaints received by 1–800–MEDICARE included beneficiaries who called 1–800–MEDICARE to inform the Agency via the toll-free line that agents failed to inform the beneficiary that their doctors were not in the MA plan's network, were inaccurately told that there would be no costs, or were inappropriately told that their existing coverage would not be affected by enrolling into a new MA or Part D plan. During CMS' review of the telephonic enrollment audio recordings between beneficiaries and agents, it was clear that some beneficiaries were confused that their current coverage would be ending. It also was clear that some were misled by the agent and were told that their existing benefits would not change, and others were never informed by the agent that enrollment into an MA or Part D plan would cancel the beneficiary's current coverage. There also were cases where the agent failed to go over the beneficiary's current providers or Part D drugs. In addition, few, if any, calls with agents included explanations that all of the benefits and cost sharing for the plan could be found in the plan's Evidence of Coverage.

By requiring the PECL to be reviewed with prospective enrollees as part of telephonic enrollments, we hope to ensure that beneficiaries are better informed about the details surrounding the plan for which they are enrolling. Under this proposal, MA organizations and Part D sponsors would decide whether they require their contracted agents and brokers to read the PECL in its entirety or to require that each item contained on the PECL be discussed. It is CMS' expectation that the agent ensures the beneficiary understands the items in the PECL. Agents may do this by receiving an affirmative answer to whether the prospective enrollee understands the information provided, as well as asking the prospective enrollee if she or he has any questions. CMS believes that an actual review of the PECL elements with prospective enrollees will decrease inaccurate information and misunderstandings, resulting in fewer 1–800–MEDICARE complaints and higher beneficiary satisfaction.

Therefore, CMS is proposing to add the reference to ''Effect on current coverage'' to §§ 422.2267(e)(4)(viii) and 423.2267(e)(4)(viii) and requiring, in §§ 422.2267(e)(4) and 423.2267(e)(4), that the PECL be reviewed with the prospective enrollee during telephonic enrollments.

CMS also is proposing a change to § 422.2267(e)(5)(ii)(A) to require Summary of Benefits medical benefits be listed in the top half of the first page and in the order currently listed in §§ 422.2267(e)(5)(ii)(A)(1) through 422.2267(e)(5)(ii)(A)(10). Currently, § 422.2267(c)(2) states that model materials, like the Summary of Benefits, must follow CMS' order of content when specified. This existing regulation permits CMS to specify the order of content presented in MA required model materials. CMS has already specified the order of information on medical benefits in the Summary of Benefits instructions, mirroring the regulatory list of medical benefits provided at § 422.2267(e)(5)(ii)(A)(1) through (10). By requiring all plans to list certain benefits in the same location and in a specified order, beneficiaries will be able to more easily compare benefits across different plans and in a more standardized way. The ability for beneficiaries to review and compare benefits across different MA Plans will assist beneficiaries in making a more informed health care choice.

We are also proposing a change to 42 CFR 422.2267(e)(10) and 423.2267(e)(13), which provides that the non-renewal notice is a model communications material through which plans must provide the information required under §§ 422.506 and 423.507, respectively. Per §§ 422.2267(c) and 423.2267(c), model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. Modifications to model materials, including the non-renewal notice, can be made at the MA organization's/Part D sponsor's discretion within certain limits outlined in §§ 422.2267(c) and 423.2267(c). Our current non-renewal document and accompanying instructions do not permit plan changes, except where noted, to the non-renewal notice. To ensure accuracy and consistency, we are proposing to update §§ 422.2267(e)(10) and 423.2267(e)(13) to specify that the non-renewal notice is a ''standardized communications material'' so that it is clear these materials must be used without modifications except where noted. This is necessary to ensure that the vital information contained in the non-renewal notice about a beneficiary's alternative healthcare options and the timing for the plan to make a selection are conveyed in a way that CMS has determined is accurate and understandable. Beneficiaries receiving the non-renewal notice are provided a Special Enrollment Period (SEP) (as per § 422.62(b)(1)) with deadlines to make new health care decisions. This notice provides beneficiaries with this information, as well as other plans available to them. As a model notice, MA organizations/Part D sponsors would be able to place this vital information anywhere in the document,

potentially highlighting their other plan options, instead of providing equal prominence to all health care choices. Our proposal would eliminate that possibility.

In the May 2022 final rule, CMS implemented a Third Party Marketing Organization (TPMO) disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41). The required disclaimer states, ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact *Medicare.gov* or 1–800–MEDICARE to get information on all of your options.'' We currently require TPMOs that represent more than one MA or Part D plan in a given service area, but do not represent all plans, to verbally convey the disclaimer within the first minute of a sales call, electronically convey the disclaimer when communicating with a beneficiary via email or online chat, or prominently display the disclaimer on their website, and to include the disclaimer on all marketing materials. We are proposing to modify this disclaimer to add State Health Insurance Programs (SHIPs) as a source of information for beneficiaries. We are also proposing that an additional disclaimer requirement, which would require all TPMOs to list names of the MA organizations or Part D sponsors with which they contract in the applicable service area.

Although TPMOs may contract with one or more MA organizations and Part D sponsors, they do not necessarily contract with all available options in a service area. When a beneficiary contacts a TPMO that does not contact with all MA organizations or Part D sponsors in a particular service area, the beneficiary may not know that the TPMO does not sell or represent all of the available options. To ensure beneficiaries in this situation are aware that other options exist, the disclaimers at §§ 422.2267(e)(41) and 423.2267(e)(41) require TPMOs to notify the beneficiary that a complete list of plans could be obtained from 1–800–MEDICARE or *Medicare.gov*. We are proposing to modify §§ 422.2267(e)(41) and 423.2267(e)(41) to provide that TPMOs in this situation also notify beneficiaries that they may contact their local SHIP for more information. SHIPs are another resource that beneficiaries can contact to obtain unbiased information on all available health and drug plan options. We believe adding SHIPs to this disclaimer provides beneficiaries with important and unbiased information regarding other sources of assistance.

In addition, CMS is proposing that TPMOs disclose the names of the MA organizations or Part D sponsors with which they contract. This ensures that beneficiaries are aware of all of their choices when communicating a TPMO. In CMS's review of hundreds of sales, marketing, and enrollment audio calls, CMS found over 80% of the calls only mentioned one plan option from one MA organization. The audio reviews CMS conducted also showed that agents rarely, if ever, informed the beneficiary that there were multiple plans available in the service area. Although the agent may have researched other plans on behalf of the beneficiary the agent was assisting, information about those plan options was rarely communicated to the beneficiary, and thus the beneficiary may not have known about their other options to make an informed decision about the plan that best meets the beneficiary's needs.

CMS is proposing to revise the existing TPMO disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41) to require TPMOs that do not contract with every available MA organization or Part D sponsor in a service area to include a list the MA organizations or Part D sponsors with which they do contract in the beneficiary's service area. In addition, because the existing TPMO disclaimer at §§ 422.2267(e)(41) and 423.2267(e)(41) does not apply to TPMOs that contract with every MA organization or Part D sponsor in a given service area, CMS is also proposing to revise §§ 422.2267(e)(41) and 423.2267(e)(41) to include a new disclaimer for TPMOs that do contract with every MA organization or Part D sponsor in the service area. This new disclaimer would need to be provided within the first minute of the call, as required for TPMOs that do not contract with MA organization or Part D sponsor in a service area. As with the existing TPMO disclaimer, this new disclaimer would need to be electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means, prominently displayed on the TPMO's website, and included in any TPMO marketing materials, including print materials and television advertising.

Therefore, we propose modifying §§ 422.2267(e)(41) and 423.2267(e)(41), to require two disclaimers. The first disclaimer, which applies to TPMOs that do not sell for all MA organizations or Part D sponsors in a service area, would read, ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area which are [insert list of MA organizations or Part D sponsors]. Please contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program to get information on all of your options.'' The second disclaimer, for those TPMOs that sell for all MA organizations or Part D sponsors in a service area, would read, ''We offer the following plans in your area [insert list of MA organizations or Part D sponsors]. You can always contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program for help with plan choices.''

We are proposing a technical change to § 423.2267(e) to add new paragraphs (e)(43) and (e)(44), to include the comprehensive medication review (CMR) written summary which, in accordance with § 423.153(d)(1)(vii)(B), Part D sponsors must provide to all MTM program enrollees who receive a CMR, as well as the safe disposal information that, in accordance with § 423.153(d)(1)(vii)(E), Part D sponsors must provide to all plan enrollees targeted for MTM. As noted in the January 2021 final rule (86 FR 5984), we intended § 423.2267(e) to be a complete list of all required materials and content. The CMR written summary and safe disposal information are materials that Part D sponsors are already required to provide under existing regulations at 42 CFR 423.153(d)(1)(vii)(B) and (E), and were inadvertently omitted from this section during the previous rulemaking. Because MA–PDs must comply with Part D regulations per § 422.500, this proposal regarding the MTM and safe disposal instructions will also apply to MA–PDs.

Based on our review of complaints and audio calls, we are concerned about the level of oversight that MA organizations and Part D sponsors provide over their contracted agents and brokers. In our review of complaints and discussions with MA organizations and Part D sponsors, MA organizations and Part D sponsors appear to be reactive instead of proactive in addressing inappropriate agent and broker behavior. CMS has received complaints through 1–800–MEDICARE as well as other CMS staff. Once a complaint is received, the complaint is provided to the applicable MA organization or Part D sponsor to review, investigate, and take appropriate action. However, this method of oversight is more reactive, and requires organizations and sponsors to respond to issues that CMS has already been made aware. As a result, we are concerned that inappropriate behavior by agents and brokers is not being sufficiently addressed and corrected by MA organizations and Part D sponsors. In §§ 422.2272 and 423.2272, we propose requiring

sponsoring organizations have an agent and broker monitoring and oversight plan that ensures agents and brokers are adhering to CMS requirements and that the MA organization or Part D sponsor is actively monitoring and reporting agents and brokers to CMS who are not compliant with CMS requirements.

We believe a thorough oversight and monitoring plan will assist in identifying and stopping poor performing agents and brokers more quickly, whether they are independent, captive, or employed agents or brokers. To that end, CMS requires MA organizations and Part D sponsors to oversee the agent and brokers with which they contract (§§ 422.2274(c) and 423.2274(c)). A proper oversight program includes the review of internal grievances, 1–800–MEDICARE complaints, random samplings of past audio calls, listening to sales/marketing/enrollment calls in real-time, secretly shopping in-person education and sales events, and secretly shopping web-based education and sales events. These types of activities will improve the overall marketing and sales activities of plans. MA organizations and Part D sponsors should be able to identify areas where agents and brokers have not been adequately trained, agents and brokers who may not fully understand the product offerings, and agents and brokers who improperly market to beneficiaries. MA organizations and Part D sponsors can then quickly act, such as tailored training or disciplinary measures, based on the specific issues for each agent or broker. Once an MA organization or Part D sponsor identifies the non-compliance, the MA organization or Part D sponsor would then be required to report that agent or broker non-compliance to CMS. This will assist plans and sponsors in gauging the scope of marketing issues, and help plans and sponsors in developing methods to stop inappropriate agent and broker activity. Therefore, we are proposing to add a new (e) to §§ 422.2272 and 423.2272 to read, ''Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.''

Section 1856(b) of the Act provides CMS the authority to publish regulations creating standards for organizations to carry out the MA program. CMS is proposing to adopt, at a new paragraph (c)(12) of §§ 422.2274 and 423.2274, additional standards for agents and brokers in their marketing of MA and Part D plans to beneficiaries to require that sponsoring organizations ensure that agents and brokers discuss specific topics and information with beneficiaries prior to enrollment. We believe that adopting these standards is consistent with and achieves a similar goal as the statutory requirement in section 1851(j)(2)(D) of the Act that compensation to agents and brokers create incentives for agents and brokers to enroll beneficiaries in the plan that best meets their health care needs. For an agent or broker to ensure the beneficiary is in a plan that best meets their needs, the agent or broker needs to obtain enough information to determine the health care needs of the beneficiary. If the agent or broker fails to have sufficient information to ensure that he or she is enrolling the beneficiary in a plan that best meets the beneficiary's health care needs, but is compensated for enrolling the beneficiary in a plan, we believe that section 1851(j)(2)(D) of the Act is undermined. CMS is concerned that agents and brokers too often fail to adequately determine the kind of health plan into which a beneficiary wishes to enroll, such as a plan that offers a lower premium and higher copays, one that has specific providers in their network, or one that provides coverage for a certain durable medical equipment. Therefore, in §§ 422.2274(c) and 423.2274(c), we are proposing that all agents and brokers (employed, captive, and independent agents) go through a CMS-developed list of items that must be asked and/or discussed during the marketing and sale of an MA plan or Part D plan.

CMS has listened to hundreds of marketing and enrollment audio calls. In the majority of these calls (over 80 percent), agents and brokers failed to ask pertinent questions to help a beneficiary enroll in a plan that best meets his or her needs. CMS listened to calls where the agent or broker only asked about primary care providers and prescription drugs. There were also calls that CMS listened to where the agent or broker only discussed ''extra benefits'' such as dental and vision. During many of the calls CMS reviewed, the agent or broker failed to ask important questions, such as whether there was a specialist that the beneficiary wished to see (or currently sees) and whether that specialist was in the plan's network, whether the beneficiary would prefer lower copays and a higher premium or vice versa, which hospitals the beneficiary preferred, or whether the beneficiary wanted dental and hearing benefits. Some calls were under twenty (20) minutes in length. This short time period led CMS to question whether an agent or broker could have realistically obtained the necessary information from the beneficiary in order to adequately determine their needs and wants, review available options, and complete the enrollment.

In order to properly assist a beneficiary in choosing a Medicare health and/or drug plan, the agent or broker must have sufficient information about the beneficiary's needs and goals. We do not believe a beneficiary can be enrolled in a plan that best meets his or her needs when, for example, an agent or broker fails to ask the beneficiary about their current providers, including specialists and preferred hospitals or other facilities. To ensure a beneficiary's needs are reviewed, CMS is proposing to add a new (12) to §§ 422.2274(c) and 423.2274(c), requiring an MA organization or Part D sponsor ensure that the agent's/broker's sales call goes over each CMS required question or topic, including information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs. CMS would provide in sub-regulatory guidance more detailed questions and areas to be covered based on these general topics.

If agents and brokers are required to ask beneficiaries certain questions, or cover certain topics, prior to beginning the enrollment process, we expect that beneficiaries will be more knowledgeable about the plans that are available to them, and thus better able to make an informed choice. We are not proposing that agents or brokers would be required to read standardized questions or statements regarding the topics discussed here. Rather, we are proposing that certain required topics are addressed, prior to the enrollment, whether it be asking questions about the medications the beneficiary takes or covering topics such as the premium the beneficiary will be charged for the plan. We propose to add a new (12) to §§ 422.2274(c) and 423.2274(c) which will read, ''Ensure, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs.'' or

''Ensure, prior to an enrollment CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), premiums, and other services (such as over-the-counter medications and other incentives).''

Currently in §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii), TPMOs must record all calls with beneficiaries. This regulation was put into effect to ensure that TPMOs, including agents and brokers, were appropriately marketing to beneficiaries. As stated above, CMS's experience with reviewing complaints and in listening to recorded calls revealed many instances where agents and brokers have failed to provide enough information, confused beneficiaries, and, most concerning, provided inaccurate information about plan benefits. In other cases, these entities led beneficiaries to believe the beneficiaries were calling Medicare rather than an insurance agent. This requirement for recording all calls with beneficiaries was proposed on January 6, 2022, and finalized in the May 2022 final rule; we had received few pertinent comments prior to the rule being finalized. However, following this rule, CMS has heard from trade organizations, plans, as well as individual agents regarding the obligation to record all calls. Many of these post-final rule questions and comments centered around whether ''smaller'' agent companies had to record conversations. Some of the comments received after the final rule requested clarification on whether all calls really needed to be recorded.

CMS is not proposing to change the requirement that TPMOs, including agents and brokers, regardless of their size, must record calls. However, we are proposing to limit calls that must be recorded from all calls to only those calls regarding sales, marketing, and enrollment. CMS believes the current requirement is too broad because under the current requirement calls placed to merely set up an in-person meeting, make sure the beneficiary received the plan welcome packet, or ask non-marketing questions, such as when the plan will be effective, must all be recorded. We believe this is an unnecessary burden since our goal is to obtain call recordings to ensure the marketing, sales, and enrollment activities conducted by agents, brokers and TPMOs meet the applicable regulatory requirements. Therefore, we are proposing to modify §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to limit the calls that must be recorded to the complete duration of marketing, sales, and enrollment calls. The definition of marketing in §§ 422.2260 and 423.2260 will apply to new paragraph (g)(2)(ii) and we intend the words ''sales'' and ''enrollment'' to include the plain meaning of those terms.

In addition to modifying §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to only require marketing, sales, and enrollment calls to be recorded, we are also proposing to add language to clarify the platform(s) of calls which much be recorded. Since implementing the May 2022 final rule, we have received questions asking whether technology-based meetings (for example, Zoom meetings) need to be recorded. CMS considers meetings taking place on Zoom, Facetime, Skype, or other technology-based platforms to be the same as telephonic calls with the same concerns as telephonic calls. Technology is changing the way people interact and Medicare beneficiaries aging into the program are more likely to have experienced newer technologies and may be more comfortable using technology. In addition, during the COVID–19 pandemic, many beneficiaries learned to use different technologies to keep in touch with people. Moreover, because of the pandemic, many agents and brokers have moved to using these newer technologies, holding meetings through web-based technologies.

Based on the reasons stated above, we propose to modify §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to read ''Record all marketing, sales, and enrollment calls, including calls occurring via web-based technology, in their entirety.''

Finally, in §§ 422.2274(g) and 423,2274(g), we are proposing to add a new paragraph (4) to address issues with TPMOs distributing beneficiary contact information to multiple entities, in any manner, including selling this information. When a beneficiary calls a 1–800 number from a direct mail flyer, a television advertisement, or an internet advertisement, the beneficiary most likely believes they are only calling—and requesting contact with—the entity that answers the call. However, some of these entities, in quickly read disclaimers or through disclaimers in very small print, that actually inform the beneficiary that their information may be sold to other entities. The contact information (name, address, phone number) obtained by these entities is then sold to one or more field marketing organizations and/or agents/brokers. In turn, these other entities then call the beneficiary, using the initial incoming call and the contact information obtained by the TPMO from that incoming call, as a form of permission to reach out and contact the beneficiary.

When a beneficiary calls a company based on an advertisement, CMS asserts that the beneficiary is only expecting to connect with that particular company, not to have return calls made to their personal home or cell number from other companies. Through environmental scanning efforts, however, CMS has learned that the selling and reselling of beneficiary contact information is happening as described here and that beneficiaries are unaware that by placing the call or clicking on the web-link they are unwittingly agreeing for their contact information to be collected and sold to other entities and providing consent for future marketing activities.

We do not believe beneficiaries knowingly give their permission to receive multiple calls from multiple different entities on the basis of a single call made by a beneficiary. We believe beneficiaries intend in these scenarios that their information will be received only by one entity, that being the plan that will ultimately receive the beneficiary's enrollment request. Additionally, providing a quickly-read disclaimer or providing a disclaimer in very small print or in an inconspicuous place when that disclaimer indicates that a beneficiary's contact information may be provided or sold to another party, are considered misleading marketing tactics because these entities are using beneficiary data and contact information in a manner in which the beneficiary did not intend. Organizations that require the beneficiary to agree to allowing their contact information to be resold prior to speaking with a representative or having access to any information are another example of this. In these situations, a beneficiary initiates contact with one organization and then ends up receiving calls from multiple other unrelated entities. In light of the statutory prohibition on unsolicited contact (§§ 1851(j)(1)(A) and 1860D–04(l)(1)), and the regulatory interpretation of that prohibition (§§ 422.2264(a)(3) and 423.2264(a)(3)), this practice goes beyond the scope of what we consider permissible. Therefore, we are proposing to add a new (4) to §§ 422.2274(g) and 423.2274(g) to read, ''Personal beneficiary data collected by

a TPMO may not be distributed to other TPMOs.''

We solicit comment on these marketing and communications proposals and whether the proposed regulatory changes will sufficiently achieve the goals we have outlined of protecting beneficiaries.

Q. Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

1. Overview and Summary

We propose regulatory changes regarding (1) obtaining approval to make changes to a formulary already approved by CMS—including extending the scope of immediate substitutions; and (2) providing notice of such changes.

In section III.Q.2.b. of this proposed rule, Approval of Changes to Approved Formularies, we propose to codify longstanding sub-regulatory guidance and terminology (such as classification of changes as either maintenance or non-maintenance) that specify when and how Part D sponsors obtain approval to make negative formulary changes and the enrollees to whom these changes would apply. Section III.Q.2.b.(3). of this proposed rule includes our proposal to permit Part D sponsors that meet certain requirements to immediately substitute a new interchangeable biological product for its corresponding reference product; a new unbranded biological product for its corresponding brand name biological product; or a new authorized generic for its corresponding brand name equivalent. Section III.Q.2.b.(3). of this proposed rule also includes a proposal for a third category of negative formulary changes defined as immediate negative formulary changes.

Currently, we exempt Part D sponsors that make immediate generic substitutions under the regulation from providing transition supplies; we now propose in section III.Q.2.b.(3). of this proposed rule to exempt Part D sponsors making any immediate negative formulary changes (that is, all types of immediate substitutions and also market withdrawals) from providing transition supplies. We also propose to conform our regulations to provide that the same timing rules would apply for all immediate negative formulary changes, that is they all could take place at any time.

Section III.Q.3. of this proposed rule proposes to align our regulatory requirements for appropriate advance notice of formulary changes to guidance and longstanding operations, including streamlining certain requirements.

2. Approval of Changes to Approved Formularies

a. Background: Statutes, Regulations, and Longstanding Operational Implementation of Changes to Approved Formularies

Section 1860D–11(e)(2) of the Act provides that the Secretary may only approve Part D plans if certain requirements are met, including the provision of qualified prescription drug coverage.[112] Section 1860D–11(e)(2)(D) of the Act specifically predicates approval on a finding by the Secretary that plan design, including formulary and tiered formulary structure, is not likely to substantially discourage enrollment by certain Part D eligible individuals. Section 1860D–4(c)(1)(A) of the Act calls for ''a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate.'' [113]

We have taken a number of steps to implement the approval process. For instance, under § 423.272(b)(2)(i), CMS does not approve a bid for which the plan design and benefits (including any formulary and tiered formulary structure) or utilization management program are likely to substantially discourage enrollment by certain individuals. There are also regulations specific to the development and content of formularies. For example, § 423.120(b)(1) requires Part D sponsors to establish pharmacy and therapeutic committees to develop and review formularies as specified, and § 423.120(b)(2) requires provision of an adequate formulary.

Each year we undertake a multi-step process to review and approve all formularies submitted by Part D sponsors as part of their annual bid packages. We review each formulary, and associated utilization management tools, to ensure that they do not discourage enrollment by beneficiaries with certain types of disease states. We do this by utilizing formulary review checks such as: provision of drugs across different classes and categories per §§ 423.120(b)(2)(i), (ii), and (iv) and 423.272(b)(2); consistency with best practice formularies currently in widespread use; clinical merit per § 423.120(b)(1)(v); and treatment guidelines for disease states in § 423.120(b)(2)(iii). As part of the process, we reach out to Part D sponsors when necessary to provide an opportunity to address any issues identified during our review prior to final approval.

The statute contemplates changes to approved formularies: section 1860D–4(b)(3)(E) of the Act specifies that Part D sponsors may remove a covered Part D drug or change its preferred or tiered cost-sharing status after providing appropriate notice. We understand that the statute does not contemplate a static formulary. Prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, evidence-based clinical guidelines, and opportunities for improving safety and quality in prescription drug use at a lower cost will inevitably occur over the course of the year.

Realizing that implementing new developments may require formulary changes, we support formulary changes that would allow enrollees to quickly benefit from the latest clinical research, new potentially lower-cost options, or possibly result in better health outcomes. For instance, § 423.120(b)(5)(iii) permits Part D sponsors to immediately remove drugs from their formularies when Food & Drug Administration (FDA) deems them unsafe and drug manufacturers remove them from the market. Similarly, § 423.120(b)(5)(iv) permits a Part D sponsor that adds an equivalent generic drug, and otherwise meets requirements, to immediately remove a brand name drug or change its preferred or tiered cost-sharing status. In addition, in the final rule titled ''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,'' which appeared in the April 16, 2018 **Federal Register** (hereinafter referred to as the April 2018 final rule), we reduced the time for advance direct notice of certain formulary changes from 60 to 30 days.

That said, as discussed at section III.M. of this proposed rule, midyear changes to the Part D benefit can violate uniformity and undermine the integrity of bids. And despite the statute's contemplation of changes in the tiered or preferred cost sharing status of a specific drug, which accords with the goal of providing an opportunity for Part D sponsors to respond to new information specific to a particular drug by making changes that could result in

[112] Section 1860D–4 of the Act on beneficiary protections for qualified prescription drug coverage includes requirements for beneficiary access such as the development and application of formularies. For instance, under section 1860D–4(b)(3)(B) of the Act, the pharmacy and therapeutic committee of each Part D sponsor must base clinical decisions on certain scientific evidence and standards of practice, while subparagraphs (C) and (G) of section 1860D–4(b)(3) of the Act require formularies to include drugs within certain categories and classes.

[113] See discussion in the January 2005 Part D final rule (70 FR at 4299).

better treatment for enrollees, the statute does not contemplate allowing plans to make large scale changes to their formularies after they have undergone the robust approval process described above. Permitting large scale formulary changes midyear could lead to ''bait and switch'' concerns. During open enrollment, beneficiaries decide whether to enroll (or remain) in particular plans based on the benefit, including drugs offered on the formulary and tier placement, and as represented to them by the Part D sponsor. Formulary stability is extremely important so that enrollees maintain access to the benefit they chose. Moving too often from one drug to a different drug for non-clinical reasons could also pose undue threats to enrollee health. Indeed, the current regulation, § 423.120(b)(6), prohibits Part D sponsors from removing drugs or making changes to preferred or tiered cost-sharing status between open enrollment up through the first 60 days of the contract year except as specified.[114]

To balance the need for a rigorously vetted, stable formulary against the need to permit formulary changes that respond to developments such as new drug therapies and knowledge, we have, since the start of the program, permitted certain drug-specific changes to approved formularies.

Our process for reviewing and approving changes to approved formularies can be broken out into several categories, each of which is subject to a different level of CMS review and/or approval. Consistent with existing Chapter 6 of the Prescription Drug Benefit Manual (PDBM), we are proposing to codify our process for review and approval of changes to approved formularies.

b. Proposed Provisions for Approval of Formulary Changes

In this rule, we propose to define several types of formulary changes, adopt rules for CMS approval of negative formulary changes, revise requirements for implementation of certain formulary changes that may be made immediately, and update and streamline our notice requirements. As part of this proposal, we are proposing organizational changes to the existing regulations to streamline them and improve their clarity.

(1) Proposed Definitions

In our existing guidance in PDBM Chapter 6, we use the term ''negative formulary change'' and categorize negative formulary changes as either ''maintenance'' or ''non-maintenance.'' Our policies with respect to the form of sponsor submission, means of CMS approval, and which individuals are considered to be affected by an approved formulary change differ as between ''maintenance'' and ''non-maintenance'' negative formulary changes. We now propose to codify our existing policy with respect to negative changes to approved formularies, including when and how notice must be provided to ''affected enrollees.''

In § 423.100 we propose to define negative formulary changes as the following changes with respect to a Part D drug: (1) removing the drug from a formulary; (2) moving the drug to a higher cost-sharing tier; or (3) adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limits (QL) requirements for the drug. We would note that QL restrictions would not include safety edits described at § 423.153(c)(2) to prevent unsafe or inappropriate dosing of drugs. CMS does not require such edits to be submitted to CMS as part of the formulary. Accordingly, we propose that negative formulary changes do not include safety-based claim edits which are not submitted to CMS. (See section IV.W.2. of this proposed rule on Codifying Current Part D Transition and Continuity of Care Policies for the proposal to define safety-based claim edits.) Negative formulary changes would, however, include adding PA, ST, or QL to apply to a drug for the first time, making existing applicable PA or ST requirements more restrictive, or making QL edits more restrictive by reducing allowances (for instance, reducing a daily dose from two tablets per day to one tablet per day) unless the reduction is a safety edit as described above.

In § 423.100, we propose to update the definition of ''affected enrollee'' to reference beneficiaries affected by all negative formulary changes instead of just removal or change in preferred or tiered cost-sharing status.

PDBM Chapter 6 also classifies negative formulary changes as either maintenance or non-maintenance changes. Maintenance changes are changes generally expected to pose a minimal risk of disrupting drug therapy or are warranted to address safety concerns or administrative needs (for example, drug availability such as shortages and determining appropriate payment such as coverage under Part B or Part D). In our experience the vast majority of negative formulary changes are ''maintenance'' changes that CMS routinely approves, and the vast majority of maintenance changes are generic substitutions, in which the Part D sponsor removes a brand name drug and adds its generic equivalent.

Consistent with our current manual policy and operations, we propose at § 423.100 to define ''maintenance changes'' to mean the following negative formulary changes: (1) making any negative formulary changes to a drug and at the same time adding a corresponding drug at the same or lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements (other than those meeting the requirements of immediate substitutions currently permitted and that we propose to permit below); (2) removing a non-Part D drug; (3) adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning; (4) removing a drug deemed unsafe by FDA or withdrawn from sale by the manufacturer if the Part D sponsor chooses not to treat it as an immediate negative formulary change; (5) removing a drug based on long-term shortage and market availability; (6) making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization; or (7) adding PA to help determine Part B versus Part D coverage. We additionally intend through the use of the plural tense to clarify that Part D sponsors may request to apply more than one negative formulary change simultaneously to that drug.

Non-maintenance changes, which are infrequently warranted, are negative formulary changes that limit access to a specific drug without implementing a corresponding offset (such as adding an equivalent drug) or addressing safety or administrative needs. We propose to define ''non-maintenance change'' at § 423.100 to mean a negative formulary change that is not a maintenance change or (as discussed in the next paragraph) an immediate negative formulary change.

To these two longstanding categories of negative formulary changes, maintenance and non-maintenance, we would introduce in § 423.100 a third category to capture negative formulary changes that fall within certain parameters and that may be made immediately. We propose to define ''immediate negative formulary changes'' as those which meet the requirements as either an immediate substitution or market withdrawal

[114] Section 423.120(b)(6) exempts § 423.120(b)(5)(iii) and (iv), which permit Part D sponsors to immediately remove drugs deemed unsafe by FDA or withdrawn by their manufacturers or make immediate generic substitutions as specified.

under § 423.120(e)(2)(i) or (ii) respectively. We note, however, that while such changes may be made immediately, Part D sponsors retain the option to implement such changes as maintenance changes. This means, those Part D sponsors that can meet all applicable requirements would have a choice as to whether to make such changes immediately and thereafter provide notice of specific changes or submit a negative change request and provide specific notice of such changes 30 days before they occur.

To effectuate our proposal, discussed in section III.Q.2.b.(3). of this proposed rule, to permit certain immediate substitutions in the case of authorized generics, interchangeable biological products, and unbranded biological products, we propose to define ''corresponding drug'' in § 423.100 to mean, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference biological product, or an unbranded biological product of a biological product.

Finally, we propose to move our current regulatory description of ''other specified entities'' currently in § 423.120(b)(5)(i) to be a standalone definition of the term in § 423.100 that lists State Pharmaceutical Assistant Programs (SPAPs), entities providing other prescription drug coverage, prescribers, network pharmacies, and pharmacists as specified.

(2) Proposed Approval and Implementation of Maintenance and Non-Maintenance Changes

We propose to codify our existing practice with respect to CMS review and approval of negative formulary changes. Specifically, we propose in § 423.120(e) that Part D sponsors may not make any negative formulary changes to the CMS-approved formulary except as specified in the regulation. We would maintain our existing requirements for immediate implementation of certain formulary changes for immediate substitutions and market withdrawals at § 423.120(e)(2), with some modifications, as discussed in section III.Q.2.b.(3). of this proposed rule.

We propose to codify our existing policy with respect to maintenance changes, which would, at proposed § 423.120(e)(3)(i), permit Part D sponsors that have submitted a maintenance change request to assume that CMS has approved their negative change request if they do not hear from CMS within 30 days of submission. We propose to codify our existing policy with respect to non-maintenance changes as well, which would specify at § 423.120(e)(3)(ii) that Part D sponsors must not implement non-maintenance changes until they receive notice of approval from CMS. We also propose to codify our longstanding policy that affected enrollees are exempt from approved non-maintenance changes for the remainder of the contract year at § 423.120(e)(3)(ii).

As discussed further in section III.Q.2.b.(3). of this proposed rule, we also propose revisions to our current requirement at § 423.120(b)(6), which prohibits Part D sponsors from making certain changes between the beginning of the annual election period until 60 days after the beginning of their contract year to reference negative formulary changes and to appear at § 423.120(e)(4).

(3) Immediate Negative Formulary Changes

Under current regulations at § 423.120(b)(5)(iv), a Part D sponsor meeting certain requirements can add a new equivalent generic drug to its formulary and immediately remove a brand name drug or change its preferred or tiered cost-sharing and then provide retrospective direct notice to affected enrollees. Such generic substitutions are exempt from the transition process under § 423.120(b)(3)(i)(B) and are not subject to the limitation on when formulary changes may take place under § 423.120(b)(6). In addition, under current regulations at § 423.120(b)(5)(iii), Part D sponsors can immediately remove drugs deemed unsafe by FDA or withdrawn from sale by their manufacturers. As a matter of operations, CMS has most recently not required Part D sponsors to submit negative change requests for immediate generic substitutions. (Instances of drugs removed when FDA deems them unsafe or a drug manufacturer withdraws them from sale are infrequent.)

Our current immediate generic substitutions policy has generated the question of whether Part D sponsors can immediately substitute drugs in other circumstances, such as substituting an authorized generic for its brand name equivalent. A central goal of our formulary policy is to provide flexibility to Part D sponsors to substitute a drug when such substitution poses minimal risk to disrupting an enrollee's drug therapy. For this reason, we are proposing in this rule to broaden the scope of permitted immediate substitutions so that Part D plans can make such substitutions not only in the case of a generic equivalent, but also in the case of authorized generics and for certain biological products. We propose to permit immediate substitution of authorized generics for the brand name product under the same terms that are currently permitted for generic equivalents. By generic equivalents, we mean drugs approved under an Abbreviated New Drug Application (ANDA) in accordance with section 505(j) of the Federal Food, Drug, and Cosmetic Act that are therapeutically equivalent to a brand name drug. Authorized generics, as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act, are marketed under their corresponding brand name drug's New Drug Application (NDA) [115] and are the exact same drug product as their corresponding brand name drugs. We therefore propose to revise the regulation to define an authorized generic drug at § 423.4 and to include the immediate substitution of authorized generics at § 423.120(e)(2)(i).

When we first adopted the immediate substitution policy, we stated that the regulation would not apply to biological products, but that we would reconsider the issue when interchangeable biological products became available in Part D. At the time of this writing, there is at least one interchangeable biological product [116] and there is also an unbranded biological product marketed under the same license. Other licensed interchangeable biological products may become available in Part D in the future. Accordingly, we believe it is appropriate to expand our policy to include interchangeable and unbranded biological products when immediate substitution would not disrupt existing therapy. As discussed in the preamble to the proposed rule titled, ''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,'' which appeared in the November 28, 2017 **Federal Register** (82 FR 56413), in deciding to permit immediate generic substitutions without advance direct notice of specific changes to affected beneficiaries, CMS, or other specified entities, we weighed the need to maintain the continuity of a plan's formulary for beneficiaries who

[115] See FDA website entitled ''FDA List of Authorized Generic Drugs'' at: *https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs#:~:text=The%20term%20%E2%80%9Cauthorized%20generic%E2%80%9D%20drug,product%20as%20the%20branded%20product.* Accessed April 26, 2022: ''Because an authorized generic drug is marketed under the brand name drug's New Drug Application (NDA), it is not listed in FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book).''

[116] Semglee® (insulin glargine-yfgn).

sign up for plans based on the drugs offered at the time of enrollment against the need to provide Part D sponsors more flexibility to facilitate the use of new generics. Key to our decision to permit such substitutions was the fact that the rule would apply only to therapeutically equivalent generics of the affected brand name drug because such generics are the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, and quality. Congress defined ''interchangeable'' in reference to biological products, stating that interchangeable biological products ''may be substituted for the reference product without the intervention of the health care professional who prescribed the reference product.'' [117] FDA noted on a web page for consumers that this is similar to how generic drugs are routinely substituted for brand name drugs.[118]

All 50 states now permit or require substitution of interchangeable biological products for prescribed biological products when available, subject to varying requirements regarding patient and prescriber notice, documentation of the substitution, and patient savings as a result of the substitution, among other safeguards.[119] In the context of a growing market for interchangeable biological products, to follow the lead of FDA in encouraging uptake of these products, and to provide flexibility that could to lead to better management of the Part D benefit that does not impede State pharmacy practices, we propose at § 423.120(e)(2)(i) to permit Part D sponsors meeting the applicable requirements to immediately substitute a reference biological product on its formulary with the corresponding interchangeable biological product. In support of that proposal, we also propose the following definitions at § 423.4: An ''interchangeable biological product'' would mean a product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that FDA has determined to be interchangeable with a reference product in accordance with sections 351(i)(3) and 351(k)(4) of the Public Health Service Act (42 U.S.C.§ 262(i)(3) and 262(k)(4)).[120] A ''biological product'' would mean a product licensed under section 351 of the PHSA and a ''reference biological product'' would mean a product as defined in section 351(i)(4) of the PHSA.

In addition to interchangeable biological products, unbranded biological products have recently become available. In the frequently asked questions of FDA's ''Purple Book Database of Licensed Biological Products,'' available at *https://purplebooksearch.fda.gov/faqs#9,* FDA describes an ''unbranded biologic'' or ''unbranded biological product'' as an approved brand name biological product that is marketed under its approved biologics license application (BLA) without its brand name on its label. Thus, like an authorized generic, an unbranded biological product is the same product as the brand name biological product. Accordingly, since we are proposing to permit Part D sponsors to immediately substitute a brand name drug with its authorized generic version, we similarly propose at § 423.120(e)(2)(i) to permit immediate substitution, as specified, of unbranded biological products for corresponding brand name biological products. We would further propose at § 423.4 to define ''brand name biological products'' to mean biological products licensed under section 351(a) or 351(k) of the PHSA and marketed under a brand name. We also propose at § 423.4 to define ''unbranded biological products'' as biological products marketed under a licensed section 351(a) or 351(k) BLA without a brand name on its label.

We are not proposing to permit Part D sponsors to immediately substitute biosimilar products. Biosimilar products have not met additional requirements to support a demonstration of interchangeability based on further evaluation and testing of the product, as outlined by the Biologics Price Competition and Innovation (BPCI) Act. Nevertheless, we encourage Part D plan sponsors to offer more biosimilar products on their formularies.

To reflect the fact that this regulation as proposed would then permit immediate switches for more types of drugs than generic drugs, we propose to refer to all of these changes as ''immediate substitutions'' rather than ''immediate generic substitutions,'' and drugs eligible to be immediately substituted as ''corresponding drugs'' as defined in § 423.4.

Additionally, through use of the plural tense (''negative formulary change*s*''), we intend in our proposed description of immediate substitutions in § 423.120(e)(2)(i) to make clear that a Part D sponsor that otherwise meets our requirements that adds a corresponding drug and chooses to retain, rather than remove, the drug currently on its formulary may apply more than one negative formulary change to that drug (for instance, add an interchangeable biologic product to the formulary and both move the reference product currently on the formulary to a higher cost-sharing tier and add prior authorization requirements).

Our proposal would exempt negative immediate changes that meet our requirements from the negative change request and approval process discussed earlier in III.Q.2., but would require Part D sponsors to submit such changes in their next required or scheduled CMS formulary updates. We also propose to renumber § 423.120(b)(6) to appear at § 423.120(e)(4). That section currently requires that, other than immediate generic substitutions or instances in which a plan removes a drug deemed unsafe by FDA or withdrawn from sale by a manufacturer, Part D sponsors cannot remove a covered Part D drug from its formulary or make any change in the preferred or tiered cost-sharing status of a formulary drug between the beginning of the annual election period until 60 days after the beginning of their contract year. We propose to revise this provision to refer to negative formulary changes and exempt all immediate negative formulary changes—be they immediate substitutions or market withdrawals.

As noted earlier, the current regulation exempts Part D sponsors that make immediate generic substitutions from the regulatory requirement to provide transition supplies. The regulations do not specify that such an exemption exists for drugs deemed unsafe by FDA or withdrawn from sale by their manufacturers. We now propose to include market withdrawals as well as all types of immediate substitutions: § 423.120(b)(3)(i)(B) would exempt Part D sponsors making any immediate negative formulary changes from providing transition supplies of such affected drugs.

[117] PHSA § 351(i)(3) (42 U.S.C. 262(i)(3)).

[118] See ''Biosimilar and Interchangeable Biologics: More Treatment Choices'' at the following FDA website: *https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices.* Accessed April 26, 2022.

[119] Cardinal Health. Biosimilar Interchangeability Laws by State. Updated July 2021. Available from: *https://www.cardinalhealth.com/content/dam/corp/web/documents/publication/Cardinal-Health-Biosimilar-Interchangeability-Laws-by-State.pdf.*

[120] See sections 351(i)(3) and 351(k)(4) of the PHSA (42 U.S.C. 262(i)(3) and 262(k)(4)). For information current as of this writing, see ''Considerations in Demonstrating Interchangeability With a Reference Product Guidance for Industry'' at the following FDA website: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry.* Accessed September 2, 2022.

(4) Relation to Inflation Reduction Act of 2022

Section 11001 of the IRA amended section 1860D–4(b)(3)(I)(i) of Act to require the inclusion on a plan's formulary of selected drugs for which a maximum fair price is in effect with respect to the plan year. Section 1860D–4(b)(3)(I)(ii) of the Act specifies that nothing in clause (i) shall be construed as prohibiting a Part D sponsor from removing such a selected drug from a formulary if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation. We propose to identify § 423.120(e)(2)(i) as the successor regulation to § 423.120(b)(5)(iv) for purposes of section 1860D–4(b)(3)(I)(ii) of the Act.

3. Notice Requirements

a. Background: Statutes, Regulations, and Guidance on Notice of Changes

Section 1860D–4(b)(3)(E) of the Act requires Part D sponsors to provide ''appropriate notice'' to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists before removing a Part D drug from a formulary or changing the preferred or tiered cost-sharing status of such a drug. We implemented this statute in regulations issued at the start of the program in the January 2005 Part D final rule and updated in the April 2018 final rule. We consider various forms of advance notice to be appropriate in different situations, and in some cases our current regulations reflect these distinctions, such as in the case of permitted immediate generic substitutions (which we propose earlier to broaden to include other substitutions of corresponding drugs), where advance general notice is appropriate so long as direct notice is provided at a later time.

In this section of the proposed rule, we are proposing various changes to update and streamline the requirements that apply to the provision of notice of formulary changes and to propose revised requirements for appropriate advance notice of such changes. These proposals will bring our regulations into better alignment with our longstanding practice as reflected in PDBM Chapter 6.

b. Alignment of Approval and Notice Policy

We propose a series of changes to our notice requirements, both to reorganize and streamline them, as well as to provide for faster implementation of all formulary changes (other than negative formulary changes), such as moving a drug to a lower cost-sharing tier or making a utilization management tool less restrictive.

First, we propose in § 423.120(f)(1) to specify that only maintenance and non-maintenance negative formulary changes would require 30 days' advance notice to CMS and other specified entities, and in writing to affected enrollees. We are also proposing to retain at § 423.120(f)(1) an alternative option for Part D sponsors to provide an affected enrollee who requests a refill an approved month's supply of the Part D drug under the same terms as previously allowed, as well as written notice of the change. We further propose in § 423.120(f)(5)(i) to require Part D sponsors to provide advance general notice of other formulary changes to all current and prospective enrollees and other specified entities, in formulary and other applicable beneficiary communication materials advising that the formulary may change subject to CMS requirements; providing information about how to access the plan's online formulary and contact the plan; and stating that the written notice of any change made when provided would describe the specific drugs involved. For immediate substitutions, we would require information on the steps that enrollees may take to request coverage determinations and exceptions. Our current model documents already largely provide advance general notice of such changes. Section 423.120(f)(5)(ii) as proposed would further state that Part D sponsors provide enrollees and other specified entities notice of specific formulary changes by complying with §§ 423.128(d)(2) and provide CMS with notice of specific changes through formulary updates.

We propose to revise and renumber the existing regulation to specify that, except for negative immediate changes, negative formulary changes require at least 30 days advance notice. Consistent with our proposal for approval of maintenance changes, a Part D sponsor could submit the negative change request, which would constitute its notice to CMS, and notice to other specified entities at the same time. This would permit the Part D sponsor to implement the maintenance change once it is deemed approved under proposed § 423.120(e)(3)(i)—although facing the risk of sending notice of a change that is subsequently disapproved by CMS.

Part D sponsors currently submit negative change requests to CMS via HPMS that specify the negative change's intended effective date, which under our proposed approach, would have to be at least 30 days after submission for a maintenance change. However, consistent with our proposal under § 423.120(f)(3)(ii) to prohibit Part D sponsors from implementing non-maintenance changes until they receive notice of approval from CMS, Part D sponsors would not be permitted to provide notice to other specified entities or affected enrollees, or to otherwise update formularies or other materials, until CMS has approved the non-maintenance change.

We propose to update § 423.128(d)(2)(iii), to require online notice of negative formulary changes. As we observed in our April 2018 final rule (83 FR 1607 and 1608), online postings that are otherwise consistent with our requirements for notice to ''other specified entities (currently described in § 423.120(b)(5) and, as discussed in section II.W.2.b.(1). of this proposed rule, proposed to be defined in § 423.100) may constitute sufficient notice of formulary changes. Consistent with this observation and that § 423.128(d)(2)(ii) requires an online formulary to be updated monthly, our proposed revisions would clarify that the requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2).

As suggested in PDBM, Chapter 6, § 30.3.4.2, sponsors may elect to provide other specified entities an annual notice providing information on the sponsor's formulary change policy (that is, timing of notice, methods of communication with beneficiaries, and any electronic notices providers may receive at the point-of-sale regarding formulary status) and the sponsor's website where these entities can verify the formulary status of particular drugs.

c. Notice of Negative Immediate Changes

Consistent with our existing requirements for immediate generic substitutions (which we propose above to broaden to include other corresponding drugs), we propose to require advance general notice of immediate substitutions and market withdrawals at § 423.120(f)(2), followed by written notice to affected enrollees as soon as possible under § 423.120(f)(3), but by no later than the end of the month following any month in which a change takes effect.

We propose at § 423.120(f)(4) to maintain our current requirements for the contents of the direct written notice, but reorganize and renumber them for clarity. We also propose to revise the regulation at § 423.120(f)(4)(iv) to require information on appropriate alternative drugs that treat the same

condition in the same or a lower cost-sharing tier in addition to retaining the long standing requirement for information on expected cost-sharing. We are providing more flexibility by removing the requirement that the alternative drugs must be in the same therapeutic category or class: while alternative drugs are likely to be, they might not necessarily be in the same therapeutic category or class based on a plan's classification system. Therefore, we are increasing flexibility with the understanding the Part D sponsor's P&T committee would identify clinically appropriate formulary alternatives at the time the formulary change is being evaluated.

We further propose that the contents of the written notice would be the same regardless of when the notice must be provided. That is, for notices of maintenance and non-maintenance changes, which must be provided to affected enrollees at least 30 days in advance per § 423.120(f)(1), and for notices of negative immediate changes, which can be provided after the changes take effect per § 423.120(f)(3), the content of the written notice would remain largely the same. Consistent with existing requirements, the notice proposed in § 423.120(f)(4) would contain the name of the affected drug, the type of negative formulary change being made and why, alternatives and expected cost sharing, and for immediate substitutions, how an affected enrollee can obtain a coverage determination or exception.

Lastly, we propose to make conforming amendments to cross citations in §§ 423.104(d)(2)(iv)(A)(*6*) and 423.128(e)(6) as applicable that we have moved the bulk of our discussion on changes to the formulary from § 423.120(b)(5) and (6) to § 423.120(e) and (f).

4. Conclusion

We would like to take this opportunity to note that sections §§ 423.2265(c)(1)(v) and 423.2265(c)(1)(ii) respectively require Part D sponsors each year to provide a Formulary to current enrollees along with an Annual Notice of Change, for which the model language instructs enrollees to review the drug list to confirm continued coverage for their drug. However, while we do not require plans to identify specific formulary changes impacting enrollees for the next contract year, several years of experience have shown that educating beneficiaries about formulary changes helps reduce beneficiary confusion and complaints at the start of the plan year. We encourage plans, particularly those with significant formulary or benefits changes due to PBM transition, plan crosswalks, contract consolidations, or other reasons to engage in beneficiary education and outreach regarding formulary changes.

In the process of proposing the regulatory changes described in this section, we realized that the burden associated with these policies was not accurately captured in PRA package CMS–10141. This package attributed a number of hours for each plan to provide notice to CMS and other entities for removal of drugs from the Part D formulary, however, the package did not properly estimate burden at the level of granularity associated with the complete scope of negative changes, negative change requests, or providing notice to affected enrollees. In section VII.B.6. of this proposed rule, we describe burden associated with our policies related to negative formulary changes as we propose to codify them. We note that while we make this correction to the PRA package, we believe that Part D sponsors have been following the guidance provided in PDBM chapter 6 and annual formulary operations memoranda. CMS monitors negative change request submission and changes to HPMS formularies as a matter of standard operations, and we have received few complaints from beneficiaries stating they have been subject to formulary changes without proper notice. Thus, we believe that Part D sponsors have been complying with the enrollee notice component of current policy. The model notice letter for enrollees affected by negative formulary changes will be included with the associated updates to PRA package CMS–10141. With respect to impact of the current policy to the Medicare Trust Fund, Part D sponsors have been able to make negative changes to their formularies, subject to CMS guidance and oversight, since the start of the Part D program. We therefore assume that there is no net impact to the Medicare Trust Fund as a result of codifying existing policy related to negative formulary changes. We also assume there is no net impact to the Medicare Trust Fund as a result of the proposed policy permitting immediate substitution of new interchangeable biological products; unbranded biological products; and authorized generics since when the initial immediate substitution policy was adopted, there was no net impact expected, as discussed in the April 2018 final rule.

In summary, we propose regulatory changes on how to obtain approval to make changes to a formulary already approved by CMS and to provide notice of such changes. In regards to approval, we propose to codify, with some revisions, longstanding sub-regulatory guidance and terminology specifying when and how Part D sponsors can obtain approval to make negative formulary changes and the enrollees to whom these changes would apply. Specifically, we propose to codify our existing practice with respect to CMS review and approval of negative formulary changes by proposing in § 423.120(e) that Part D sponsors may not make any negative formulary changes to the CMS-approved formulary except as specified in the regulation. We would codify longstanding policy at proposed § 423.120(e)(3)(i), to permit each Part D sponsor that has submitted a maintenance change request to assume that CMS has approved its negative change request if it does not hear back from CMS within 30 days of submission, and at § 423.120(e)(3)(ii) to specify that that Part D sponsors must not implement any non-maintenance changes until they receive notice of approval from CMS. We also propose to codify our longstanding policy that affected enrollees are exempt from approved non-maintenance changes for the remainder of the contract year at § 423.120(e)(3)(i).

In support thereof, we would define ''negative formulary changes'' in § 423.100 to Part D drugs to include drug removals, moves to higher cost-sharing tiers, and adding or making more restrictive PA, ST, or QL requirements. We would specify that negative formulary changes can be classified in one of three categories, which we also propose to define in that same section as:

- ''Maintenance changes,'' which we would define to encompass seven types of changes including drug substitutions that do not meet our requirements of immediate substitutions under § 423.120(e)(2)(i); changes based on particular events such as certain FDA actions, long-term shortages, and new clinical guidelines or information or to promote safe utilization; or adding PA to help determine Part B versus Part D coverage;
- ''Non-maintenance changes,'' which we would define as negative formulary changes that are not maintenance changes or immediate negative formulary changes; or,
- ''Immediate negative formulary changes'', a newly coined term that would compass all types of immediate substitutions or market withdrawals under § 423.120(e)(2)(i) or (ii) respectively.

As an exception to the general rule requiring prior CMS approval of formulary changes, our current regulations permit immediate generic substitutions and for plans to remove drugs deemed unsafe by FDA or withdrawn from the market. We propose to move and incorporate that regulation text as follows: In § 423.120(e)(2)(i), we propose to permit what we would newly describe as immediate substitutions, which would mean Part D sponsors could immediately make generic substitutions as well as substitute a new ''interchangeable biological product'' for its corresponding reference product; a new ''unbranded biological product'' for its corresponding brand name biological product; and a new ''authorized generic'' for its corresponding brand name equivalent. We would support this proposal by defining the above quoted terms in § 423.4; identifying the corresponding relationships (including the previously permitted generic substitutions) in our definition of a ''corresponding drug'' in § 423.100; and in § 423.4 also defining ''biological product'', ''brand name biological product'', and ''reference biological product''. In proposing in § 423.120(e)(2)(ii) to continue to permit plans to immediate remove from their formulary any Part D drugs deemed unsafe by FDA or withdrawn from sale by their manufacturer, we would newly describe these changes as ''market withdrawals''. Under proposed § 423.120(e)(2), Part D sponsors meeting our requirements for immediate substitutions and market withdrawals would be able to make these changes immediately without submitting negative change requests to CMS but under proposed § 423.120(f)(2) and (3) would be required to provide advance general notice of such changes and to submit specific changes in their next required or scheduled CMS formulary updates.

We propose in respective §§ 423.120(b)(3)(i)(B) and 423.120(e)(4) to conform our regulations to provide that the same transition and timing rules would apply for all immediate negative formulary changes: as proposed all immediate negative formulary changes could take place at any time (previously this exception only applied to immediate generic substitutions and market withdrawals) and Part D sponsors would not need to provide a transition supply therefor (previously we only specified in regulation that this exception applied to immediate generic substitutions).

We also propose to move to the current regulation at § 423.120(b)(6) which prohibits Part D sponsors from making certain changes from the start of the annual enrollment period to 60 days after the beginning of the contract year: We propose to revise it at § 423.120(e)(4) to specify that plans cannot make negative formulary changes during the stated time period except, as noted earlier, for immediate negative formulary changes (that is, immediate substitutions or market withdrawals).

Miscellaneous proposed changes in § 423.100 in support of the above changes include updating the definition of ''affected enrollee'' to encompass beneficiaries affected by all negative formulary changes; and moving our current regulatory description of ''other specified entities'' from § 423.120(b)(5)(1) to be a standalone definition of the term in § 423.100.

In regards to notice, we also propose to move, with some revisions and streamlining, current regulations on notice of changes, and align them to our proposed approval requirements. Specifically, in § 423.120(f)(1) we would specify that only maintenance and non-maintenance negative formulary changes require 30 days' advance notice to CMS, other specified entities, and in written form to affected enrollees. We propose to retain and move to § 423.120(f)(1) an alternative option for Part D sponsors to provide a month's supply with notice at point of sale as specified. We would move and extend our existing requirements for immediate generic substitutions to include substitutions of corresponding drugs and market withdrawals, by proposing to require advance general notice of immediate negative formulary changes at § 423.120(f)(2), followed by written retrospective notice required under § 423.120(f)(3) to affected enrollees. We propose that this retrospective notice be provided to affected enrollees as soon as possible after a specific change, but by no later than the end of the month following any month in which a change takes effect. We propose at § 423.120(f)(4) to reorganize and renumber our current requirements for the contents of the direct written notice, and provide more flexibility by no longer restricting appropriate alternative drugs to those in the same or a lower cost-sharing tier. Our proposed revision would make clear that the contents of the written notice would be largely the same regardless of the timing: whether Part D sponsors are providing notice before making a particular change (for maintenance and non-maintenance changes under § 423.120(f)(1)) or after (for negative immediate changes under § 423.120(f)(3)). Section 423.120(f)(5) would newly specify how to provide advance general notice and specific notice of changes other than negative formulary changes.

We are also proposing conforming amendments to update § 423.128(d)(2)(iii) to require online notice of ''negative formulary changes'' and to update to cross citations in §§ 423.104(d)(2)(iv)(A)(*6*) and 423.128(e)(6) to reflect the fact we would be moving the bulk of our discussion on formulary changes from § 423.120(b)(5) and (6) to § 423.120(e) and (f). We also propose to revise text at § 423.120(b)(5) and (6) to indicate that Part D sponsors must provide notice of formulary changes and can only make changes to CMS-approved formularies as specified, respectively, in § 423.120(f) and (e).

R. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

1. MTM Eligibility Criteria (§ 423.153(d)(2))

a. Background

Section 1860D–4(c) of the Act requires all Part D sponsors to have an MTM program 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. Section 1860D–4(c)(2)(A)(ii) of the Act requires Part D sponsors to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. Since January 1, 2022, Part D sponsors are also required by section 1860D–4(c)(2)(A)(ii)(II) of the Act to target all at-risk beneficiaries (ARBs) in their Part D drug management program (DMP) for MTM.

In the January 2005 Part D final rule (70 FR 4279 through 4283), CMS codified MTM targeting criteria at § 423.153(d)(2), without further detail on the number of chronic diseases, the number of covered Part D drugs, or the annual cost threshold that would be used to identify targeted beneficiaries. In guidance provided during the Medication Therapy Management (MTM) Program User Group Discussions on May 13, 2005 and March 15, 2006, and in the HPMS Memorandum Changes to Part D Sponsors' Medication Therapy Management Program (MTMP) dated August 29, 2006, CMS initially set the annual cost threshold at $4,000 at the start of the Part D program. In the 2010 Call Letter, issued on March 30, 2009, CMS subsequently lowered the

threshold to $3,000 for 2010. This approach allowed maximum flexibility for industry to develop best practices for the provision of MTM services. After gaining Part D program experience, in the final rule titled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' (75 FR 19772 through 19776), which appeared in the **Federal Register** on April 15, 2010, CMS revised § 423.153(d)(2) by establishing more specific targeting criteria based on an enrollee's number of chronic diseases (with 2 being the minimum, and 3 being the maximum a sponsor may require), number of covered Part D drugs (with 2 being the minimum, and 8 being the maximum a sponsor may require), and estimated annual Part D drug costs greater than or equal to $3,000 for 2011, which is then increased by the annual percentage increase (API) specified in § 423.104(d)(5)(iv) to determine the annual cost threshold for 2012 and subsequent years. With those changes, CMS sought to promote greater consistency across the Part D program and allow for better evaluation and comparison of MTM programs going forward. With the exception of adding the requirement that Part D sponsors target all ARBs in their DMP for MTM as described previously, the MTM eligibility framework has not been updated since that time.

In the Draft CY 2012 Call Letter (See page 109, available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2012.pdf*), we solicited comment on evaluating and addressing disparities in the MTM eligibility criteria. Subsequently, in January 2014, we issued a proposed rule titled, ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage Program and the Medicare Prescription Drug Benefit Programs,'' (79 FR 1918) in which we proposed changes to broaden the targeting criteria to 2 or more chronic diseases (with at least one being a core chronic disease), 2 or more covered Part D drugs, and average annual cost associated with taking 2 generic drugs ($620 at that time). As discussed in the subsequent final rule, which appeared in the **Federal Register** on May 23, 2014 (79 FR 29865 through 29867), those proposals were not finalized, primarily due to the significant number of commenters that strongly opposed the broad expansion of MTM eligibility and concerns about the potential impact on plan administrative costs, beneficiary premiums, and the quality of existing MTM programs.[121] However, we stated that we would continue to evaluate information on MTM programs and monitor sponsors' compliance with the MTM requirements, with the goal of proposing revisions to the criteria in future rulemaking that would help to expand the program.

MTM eligibility rates have steadily declined over time. At the start of the Part D program, CMS expected about 25 percent of the Part D population would be eligible for MTM. By 2020, MTM eligible beneficiaries had declined to just 8 percent. In conjunction with the decreasing eligibility rate, CMS has observed near-universal convergence among Part D sponsors to the most restrictive targeting criteria currently permitted under § 423.153(d)(2). When we finalized the current regulatory requirements for targeting criteria over 12 years ago, CMS elected to give plan sponsors significant flexibility in establishing their MTM eligibility criteria. However, most plans now require 3 or more chronic diseases, 8 or more Part D drugs, and target a narrow and variable list of chronic diseases. Because plans may also limit their targeting criteria to certain diseases, drugs, or both, in addition to the low eligibility rates overall, enrollees with equivalent patient profiles (for example, same chronic diseases, same number of chronic diseases, same number of Part D drugs, and similar estimated drug costs) may or may not be eligible for MTM depending on the criteria their plan requires.[122] Under the current methodology at § 423.153(d)(2)(i)(C), the annual MTM cost threshold for 2023 will be $4,935, which also significantly limits the number of beneficiaries who are eligible to be targeted for MTM enrollment.

The high cost threshold and restrictive plan criteria have significantly reduced the MTM program size over time, and Part D enrollees with more complex drug regimens who would benefit most from MTM services are often not eligible. After an extensive review of CMS and plan-reported data, CMS has identified several issues with the current MTM targeting criteria and proposes the regulatory changes discussed in the following sections in an effort to increase MTM eligibility rates, reduce variability of MTM eligibility criteria across plans, and address disparities to ensure that those who would benefit the most from MTM services have access. Taken together, the proposed changes to the MTM program targeting criteria would balance eligibility and program size while allowing us to address specific problems identified in the Part D MTM program, including marked variability and inequitable beneficiary access to MTM services.

b. Multiple Chronic Diseases

The regulation at § 423.153(d)(2)(i)(A) specifies that to be targeted for MTM, beneficiaries must have multiple chronic diseases, with 3 chronic diseases being the maximum number a Part D sponsor may require for targeted enrollment. In the current guidance (See HPMS Memorandum Correction to Contract Year 2022 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 30, 2021), CMS identifies 9 core chronic diseases, some of which are enumerated in the statute, including conditions that are highly prevalent in the Part D population, align with common targeting practices across sponsors, and are commonly treated with Part D drugs, where MTM services could most impact therapeutic clinical outcomes. The 9 core chronic diseases are: Alzheimer's disease; bone disease-arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis); chronic congestive heart failure (CHF)*; diabetes*; dyslipidemia*; end-stage renal disease (ESRD); hypertension*; mental health (such as depression, schizophrenia, bipolar disorder, or other chronic/disabling mental health conditions); and respiratory disease (such as asthma*, chronic obstructive pulmonary disease (COPD), or other chronic lung disorders).[123] While the Act specifically names congestive heart failure (CHF), we are proposing to specify only chronic CHF as a core disease. The Act also names hyperlipidemia, but we are proposing to codify dyslipidemia as a core disease to include both chronically high (hyperlipidemia) and low (hypolipidemia) lipid levels. This list of core chronic diseases aligns with longstanding MTM guidance identifying core chronic diseases and is also consistent with the discretion granted in the statute to identify chronic diseases.

As explained in the CMS guidance, as previously cited, sponsors may target enrollees with any chronic diseases or

[121] In the proposed rule, we estimated that approximately 55 percent of Part D enrollees would have been eligible for MTM based on the proposed criteria (79 FR 1951).

[122] Medication Therapy Management in a Chronically Ill Population: Interim Report, available at *https://innovation.cms.gov/files/reports/mtm_final_report.pdf.*

[123] *denotes a disease that is enumerated in statute at section 1860D–4(c)(2)(A)(ii)(I)(aa) of the Act.

target beneficiaries with specific chronic diseases. Plans that do not target all chronic diseases should target at least 5 of the 9 core chronic diseases identified by CMS. Sponsors may also offer MTM services to an expanded population of enrollees who do not meet the eligibility criteria for targeted enrollment under § 423.153(d)(2).

Based on our review of 2020 plan-reported MTM program targeting criteria and Part D enrollment data, submitted at the contract level, 86 percent of Part D enrollees were in a plan that targeted the minimum of only 5 of the 9 core chronic diseases. In the same year, only 1 percent of the Part D population was enrolled in a plan that targeted all 9 core chronic diseases, a decrease from 3 percent in 2015. Those plans had an MTM enrollment rate of 15 percent versus the overall enrollment rate across Part D of 8 percent, based on analysis of contract year 2020 MTM plan-reported and validated beneficiary-level data.[124] Combined with CMS administrative claims data, we found that a significant proportion of the Part D population that we identified as having 3 or more core chronic conditions and using 8 or more drugs (approximately 9 million beneficiaries) were not eligible to be targeted for MTM (6 million). We estimate that approximately one-third of the ineligible beneficiaries (about 2 million) were not eligible due to variations in plan-specific targeting criteria (for example, plans targeting fewer than all of the core chronic diseases or targeting specific drug classes as opposed to all or most covered Part D maintenance drugs).

HIV/AIDS is not currently included in the list of core chronic diseases. Our analysis of 2020 data, including PDE data, Parts A and B claims data, validated beneficiary-level MTM data, and other available program data, revealed that Part D enrollees with HIV/AIDS have an average of 4 core chronic diseases (including HIV/AIDS), take 12 Part D covered drugs (including 8 maintenance drugs), and incur $40,490 in Part D annual drug spend. Many of these individuals are not eligible for MTM because their plan does not target HIV/AIDS or does not target enough of their other chronic conditions. Individuals with HIV/AIDS often have complex Part D drug regimens where medication adherence is critical, very high Part D drug costs, and multiple comorbidities, and are more likely to be members of populations affected by disparities. [125] [126] Although not currently identified as a core chronic disease, HIV/AIDS is more likely to be targeted by plans (about 10 percent of plans in 2021) than any other non-core chronic disease.

Based on our internal analyses and published literature, we propose to amend the regulations at § 423.153(d)(2) by adding a new paragraph (iii) to require all Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A). As part of the proposed new provision at § 423.153(d)(2)(iii), we also propose to codify the 9 core chronic diseases currently identified in guidance and to add HIV/AIDS, for a total of 10 core chronic diseases. Under this proposal, sponsors would maintain the flexibility to target beneficiaries with additional chronic diseases that are not identified as core chronic diseases, or to include all chronic diseases in their targeting criteria. Because we developed the existing regulations and guidance early in the Part D program, and without the benefit of substantial program experience, we initially permitted significant plan discretion in developing targeting criteria. We now have data showing that approximately 20 percent of enrollees who meet even the most restrictive criteria permitted (that is, have 3 or more chronic diseases, are taking 8 or more Part D drugs, and are likely to meet the cost threshold) are not eligible because almost all plans also adopt the most restrictive number of core chronic diseases to target (5 core chronic diseases). Accordingly, this proposed change aims to close this gap in access and better ensure that the beneficiaries who are most in need of MTM services are targeted for enrollment. By reducing the variability in targeting criteria across plans, we would eliminate situations where enrollees meet the requirement in § 423.153(d)(2)(i) of having 3 chronic diseases but are not targeted for MTM enrollment because their plan does not target their chronic diseases. This reduced variability would also allow CMS to more accurately estimate program size when calculating burden and assessing impact.

CMS solicits comment on whether we should consider including additional diseases in the core chronic diseases proposed at § 423.153(d)(2)(iii), including cancer to support the goals of the Cancer Moonshot.[127] We seek comment on broadly including cancer as a core chronic condition or alternatively including specific cancers that are likely to be treated with covered Part D drugs such as oral chemotherapies where MTM could be leveraged to improve medication adherence and support careful monitoring. In particular, we are interested in feedback from Part D sponsors, MTM providers, and prescribers, including oncologists, on any potential implications if CMS were to include cancer as a core chronic condition as part of the MTM eligibility criteria. We are also interested in comments on the impact of including any additional core chronic diseases on specialized MTM provider training and on MTM program size. We also solicit comments on whether MTM services furnished under a Part D MTM program are an effective mechanism for management of certain diseases (for example, those with high use of Part B drugs or frequently changing medication regimens) given the statutory goals of the MTM program—specifically, reducing the risk of adverse events, including adverse drug interactions, and ensuring that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use. We will consider the comments received in developing our policies with respect to targeting of core chronic diseases for the final rule.

c. Multiple Part D Drugs

Section 1860D–4(c)(2)(A)(ii) of the Act requires that targeted beneficiaries be taking multiple covered Part D drugs. The current regulation at § 423.153(d)(2)(i)(B) specifies that 8 Part D drugs is the maximum number a Part D plan sponsor may require for targeted MTM enrollment. Under current CMS guidance (See HPMS Memorandum CY 2020 Medication Therapy Management Program Guidance and Submission Instructions dated April 5, 2019), sponsors are permitted to include either all Part D drugs, all Part D maintenance drugs, or specific drug classes.

Based on our internal analyses and published literature, we propose to amend the regulations at § 423.153(d)(2) by adding a new paragraph (iii) to require all Part D sponsors to include all

[124] Part D reporting requirements (OMB Control No. 0938–0992).

[125] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Dwnld-DataSnapshot-HIV.pdf https://www.cdc.gov/hiv/group/hiv-idu.html.*

[126] Kogut SJ. Racial disparities in medication use: imperatives for managed care pharmacy. J Manag Care Spec Pharm. 2020;26(11):1468–1474. doi:10.18553/jmcp.2020.26.11.1468.

[127] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/.*

core chronic diseases when identifying enrollees who have multiple chronic diseases, as provided under paragraph § 423.153(d)(2)(i)(A). As part of this provision, we also propose to codify the 9 core chronic diseases currently identified in guidance and to add HIV/AIDS, for a total of 10 core chronic diseases. Under this proposal, sponsors would maintain the flexibility to target beneficiaries with additional chronic diseases that are not identified as core chronic diseases, or to include all chronic diseases in their targeting criteria. In 2020, only 13 percent of Part D plans (4 percent of the Part D population) included all covered Part D drugs in their criteria, while 81 percent of plans (87 percent of the Part D population) limited their criteria to chronic/maintenance drugs, and 7 percent of plans (9 percent of the Part D population) limited their criteria to specific drug classes only.

We propose to revise § 423.153(d)(2)(i)(B) to decrease the maximum number of Part D drugs a sponsor may require from 8 to 5 for plan years beginning on or after January 1, 2024. Published literature demonstrates increased risk of medication errors and increased MTM effectiveness for individuals taking only a few drugs. While there is no consensus definition of polypharmacy, concurrent and/or prolonged use of 5 or more drugs has been associated with significant increases in adverse events.[128] Decreasing the maximum number of Part D drugs a sponsor may require from 8 to 5 would serve as a more accurate proxy to help ensure that the MTM program continues to focus on individuals with more complex drug regimens and increased risk of medication therapy problems, reduce potential gaps in eligibility due to utilization disparities, and take into account Part D utilization trends. While we are proposing changes to the targeting criteria with respect to the number of Part D drugs, we note that the CMR described in § 423.153(d)(1)(vii)(B) will continue to include review of all prescription medications, over-the-counter drugs (OTCs), herbal therapies, and dietary supplements.

The statutory requirement specifying that MTM targeted beneficiaries have multiple chronic diseases and take multiple covered Part D drugs suggests that the focus of MTM should be Part D covered drugs for longer term use. Maintenance drugs are drugs that are commonly prescribed to treat a chronic disease, usually administered continuously rather than intermittently, and typically prescribed for a longer course of therapy. Beneficiaries taking maintenance medications for chronic diseases may benefit most over time from the close monitoring provided by MTM required interventions, including comprehensive medication reviews (CMRs) and routine targeted medication review assessments. Accordingly, we propose to add a new provision at § 423.153(d)(2)(iv), which would require all sponsors to include all Part D maintenance drugs in their targeting criteria beginning in 2024. Plans are currently able to include all maintenance drugs in their targeting criteria as an option in the MTM Submission Module in HPMS; however, CMS does not have guidance related to how maintenance drugs are identified for this purpose. To ensure consistency across the MTM program, we also propose that, for the purpose of identifying maintenance drugs, plans would be required to rely on information contained within a widely accepted, commercially or publicly available drug information database commonly used for this purpose, such as Medi-Span or First Databank, but would have the discretion to determine which one they use. Under this proposal, sponsors would no longer be allowed to target only specific Part D drug classes, but would be required to target all Part D maintenance drugs. However, plans would retain the option to expand their criteria by targeting all Part D drugs. CMS solicits public comment on our proposed parameters for defining maintenance drugs, including potential additional sources for making such determinations.

These proposed changes would reduce variability in MTM eligibility across plans and improve access to MTM services for Medicare Part D beneficiaries at risk of medication therapy problems. Black and Hispanic individuals tend to use fewer prescription drugs and incur lower prescription drug costs than Non-Hispanic White individuals.[129] Consequently, the Part D utilization- and cost-based MTM eligibility criteria, if set too high, may be an access barrier for those populations, as well as other populations with similar utilization patterns. Medically underserved individuals may benefit from MTM services to address potential medication therapy problems, including nonadherence. MTM services may also benefit underserved individuals through identification of un- or under-treated conditions, help with utilization of preventative therapy, or referral to needed health services. Furthermore, using 2020 data, including PDE data, Parts A and B claims data, validated beneficiary-level MTM data, and other available program data to look at the entire Part D population, we found that Part D enrollees overall have an average of 2 core chronic diseases (including the 9 core chronic diseases in the current guidance along with the proposed addition of HIV/AIDS), take 5 Part D maintenance drugs, and incur $3,931 in Part D annual drug spend (median is $617). The subset of Part D enrollees with at least one core chronic disease (including the 9 core chronic diseases in the current guidance along with the proposed addition of HIV/AIDS) have an average of 3 core chronic diseases, take 6 Part D maintenance drugs, and incur $4,595 in Part D annual drug spend (median is $899).

d. Annual Cost Threshold

Section 1860D–4(c)(2)(A)(ii) of the Act specifies that targeted beneficiaries for MTM must be likely to incur annual costs for covered Part D drugs that exceed a threshold determined by CMS. The regulation at § 423.153(d)(2)(i)(C) codifies the current cost threshold methodology, which was set at costs for covered Part D drugs greater than or equal to $3,000 for 2011, increased by the annual percentage specified in § 423.104(d)(5)(iv) for each subsequent year beginning in 2012. The annual cost threshold for 2023 will be $4,935. The cost threshold has increased substantially since it was established in regulation, while the availability of lower cost generics and the generic utilization rates have also increased significantly since the Part D program began.[130] Together, these factors have resulted in a cost threshold that is grossly misaligned with CMS' intent and inappropriately reduces MTM eligibility among Part D enrollees who have multiple chronic conditions and are taking multiple Part D drugs. The current cost threshold is more than three times the average annual cost of 8 generic Part D drugs, which is the maximum number of Part D drugs

[128] M.-C. Weng, et al., The impact of number of drugs prescribed on the risk of potentially inappropriate medication among outpatient older adults with chronic diseases, QJM: An International Journal of Medicine, Volume 106, Issue 11, November 2013, Pages 1009–1015, *https://doi.org/10.1093/qjmed/hct141.*

[129] Wang et al. Potential Health Implications of the MTM Eligibility Criteria in the Affordable Care Act Across Racial and Ethnic Groups. J Manag Care Spec Pharm. 2015 November; 21(11): 993–1003.

[130] The Part D generic dispensing rate (the total number of generic drug fills divided by the sum of generic and brand drug fills), was approximately 60 percent in 2006 and has increased steadily to a rate of 83 percent in 2019.

sponsors may require for MTM targeting under the current regulations.

The cost threshold has been identified as a significant barrier to MTM access, and, in the past, interested parties have recommended that it be lowered. CMS has found that the increasing threshold has significantly reduced MTM eligibility rates over the program's lifetime. Using 2020 data, CMS identified approximately 9 million Part D beneficiaries with 3 or more core chronic conditions and using 8 or more Part D drugs, which are the most restrictive criteria CMS currently permits. Based on validated beneficiary-level plan-reported data, about one third (approximately 3 million) of those beneficiaries were eligible for MTM, and the remaining two thirds (approximately 6 million) were not. We estimate that about 65 to 70 percent (approximately 4 million) of the ineligible beneficiaries had Part D drug costs below the MTM cost threshold based on 2020 Part D PDE data, confirming that the cost threshold substantially decreases the MTM program size.

When CMS initially codified the MTM requirements in the January 2005 Part D final rule (70 FR 4282), we noted that cost might not be the best proxy for identifying patients that could benefit most from MTM. Since that time, a robust body of published literature concludes that polypharmacy, often defined as concurrent or prolonged use of multiple drugs, increases the risk of adverse drug events. While there is no consensus definition of polypharmacy, concurrent use of 5 or more drugs is commonly cited in research studies. Although other definitions include considerations of the number of comorbid chronic disease states, drug indications, drug interactions, healthcare setting, and duration of therapy, none of these definitions include drug cost.[131] As plans continue to adopt the most restrictive eligibility criteria CMS permits with respect to the minimum number of chronic diseases and Part D drugs, lowering the cost threshold is especially important to help ensure MTM access for the targeted population contemplated in the statute. Based on published literature, comments from stakeholders, and extensive internal analysis of CMS data, we continue to believe that the cost threshold remains the biggest driver of reduced MTM eligibility rates.

Accordingly, we propose to set the MTM cost threshold for the 2024 plan year and each subsequent plan year at the average annual cost of 5 generic drugs. Based on 2020 PDE data, the annual cost of five generic drugs was approximately $1,004. Under this proposal, for 2024 and subsequent years, CMS would calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using PDE data from the plan year that ended 12 months prior to the applicable plan year, which is the PDE data currently used to determine the specialty-tier cost threshold as specified in the current provision at § 423.104(d)(2)(iv)(C). For 2024, the calculation would use PDE data from 2022 to identify the average daily cost of a generic fill, multiplied by 365 days for an annual amount. The average daily cost for a drug, would be based on the ingredient cost, dispensing fees, sales tax, and vaccine administration fees, if applicable, and would include both plan paid amounts and enrollee cost sharing. As is currently the case, the MTM cost threshold will be published in the annual Part D Bidding Instructions memo.

While the dollar amount would continue to be calculated annually, revising the methodology to base the cost threshold on the average cost of 5 generic drugs would considerably reduce year-to-year variability. Under the current methodology, the threshold amount has increased by an average of $140 each year since it was established in 2011. In contrast, the average annual cost of a generic drug, adjusted for days' supply, decreased slightly between 2012 and 2020. The proposed change to the cost threshold would also greatly reduce the likelihood that enrollees taking primarily lower cost generic alternatives would be excluded from MTM as a result of a prohibitively high cost threshold, aligning with a pillar of the Part D program: encouraging the use of generics/lower cost drugs when medically appropriate.

We propose to amend the regulation at § 423.153(d)(2)(i)(C) to reflect this new MTM cost threshold for plans years starting in 2024 and subsequent years. Specifically, we propose to set the MTM cost threshold at the average cost of 5 generic drugs, as defined at § 423.4. We also propose to codify that CMS will set the MTM cost threshold for a plan year beginning on or after January 1, 2024, by calculating the average daily cost of a generic drug using the PDE data specified at § 423.104(d)(2)(iv)(C).

e. Summary

The MTM eligibility criteria established in regulation early in the Part D program were identified based on a targeted program size. The changes we are proposing would reframe the criteria and the MTM program to focus on Part D drug utilization and beneficiaries with complex patient profiles and drug regimens, with less emphasis on high drug costs. Under our proposal, cost would continue to play a role in determining which beneficiaries must be targeted for MTM, but would no longer be the main driver of eligibility. The revisions proposed in this section would also better align MTM eligibility criteria with the statutory goals of reducing the risk of adverse events, including adverse drug interactions, and optimizing therapeutic outcomes for beneficiaries with multiple chronic conditions and who take multiple Part D drugs, while maintaining a reasonable cost criterion.

In summary, we are proposing to:

- Add a new paragraph at § 423.153(d)(2)(iii) to: (1) codify the current 9 core chronic diseases in regulation and add HIV/AIDS as a core chronic disease, for a total of 10 core chronic diseases and (2) require sponsors to include all 10 core chronic diseases in their targeting criteria;
- Revise § 423.153(d)(2)(i)(B) to lower the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs;
- Add a new paragraph at § 423.153(d)(2)(iv) to require sponsors to include all Part D maintenance drugs when determining the number of drugs an enrollee is taking for purposes of MTM eligibility; and
- Revise § 423.153(d)(2)(i)(C) to change the annual cost threshold methodology ($4,935 in 2023) to be commensurate with the average annual cost of 5 generic drugs ($1,004 in 2020). We are proposing that these changes would be applicable beginning in plan year 2024. With these proposed changes, we estimate an MTM program size of approximately 23 percent of the Part D population. Burden estimates and impacts are discussed in sections IV.X. and VIII.X. of this proposed rule, respectively.

2. Define ''unable to accept an offer to participate'' in a Comprehensive Medication Review (CMR)

Section 1860D–4(c) of the Act requires all Part D plan sponsors to have a Medication Therapy Management (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. This requirement was codified at § 423.153(d)(1) in the January 2005 Part D final rule (70 FR

[131] Mansoon, N., et al. What is polypharmacy? A systematic review of definitions. BMC Geriatrics (2017) 17:230.

4279). CMS subsequently finalized a requirement at § 423.153(d)(1)(vii)(B) specifying that, beginning in 2011, MTM programs must offer each MTM enrollee an annual CMR, including an interactive, person-to-person consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care (LTC) setting (75 FR 19772 through 19774). We included this exemption from the requirement to offer a CMR because we recognized that many LTC residents may not be able to participate in the interactive consultation due to cognitive impairment.

For 2013 and subsequent plan years, the Affordable Care Act (ACA) amended the Act by adding section 1860D–4(c)(2)(C)(i), which requires all Part D sponsors to offer all enrollees targeted for MTM an annual CMR. Consistent with the statutory change, CMS revised the regulation at § 423.153(d)(1)(vii)(B) in the April 2012 final rule (77 FR 22072) to remove the exemption for residents of LTC settings beginning in 2013. In the preamble to the final rule, we noted that the ACA provision did not provide a basis for creating an exception to the requirement to offer a CMR based on the setting of care (77 FR 22140 through 22142). However, CMS acknowledged that many LTC residents, as well as individuals in other health care settings (for example, hospice), may suffer cognitive impairments and, therefore, may not be able to participate in the CMR. Accordingly, in the same rule, we finalized a new provision at § 423.153(d)(1)(vii)(B)(2) to permit the CMR provider to perform the CMR with an enrollee's prescriber, caregiver, or other authorized individual if the enrollee is unable to accept the offer to participate.

In guidance issued annually, including our most recent HPMS guidance memorandum titled ''Correction to CY 2022 MTM Program Guidance and Submission Instructions'' dated April 30, 2021, CMS has consistently stated that we consider a beneficiary to be unable to accept an offer to participate in the CMR only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. In this proposed rule, we propose to codify this definition by amending the current regulation text at § 423.153(d)(1)(vii)(B)(2) to specify that in order for the CMR to be performed with an individual other than the beneficiary, the beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

Consistent with existing CMS guidance, the flexibility to perform the CMR with an individual other than the beneficiary would 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.

Cognitive status may be determined using interviews with the beneficiary or their authorized representative, caregiver, or prescriber. If the MTM provider determines a beneficiary is unable to accept the offer to participate in a CMR, and the MTM provider is unable to identify another individual who is able to participate, a CMR cannot be performed. However, sponsors are still required to provide the other required MTM services detailed in § 423.153(d)(1)(vii). Although claims data or diagnosis codes may be used to gather information about a beneficiary's medical conditions, Part D sponsors must not rely on such administrative information alone to determine whether a beneficiary is cognitively impaired and unable to accept the offer to participate in their own CMR.

We continue to recommend that when a targeted beneficiary moves to a LTC facility, Part D plan sponsors should identify the appropriate contact for each beneficiary. This contact could be the authorized representative, caregiver, or prescriber. Sponsors, or their MTM providers, could contact the admissions coordinator, Minimum Data Set (MDS) coordinator, Director of Nursing, or other appropriate facility staff person to ascertain if an authorized representative has been designated in the beneficiary's medical record or chart. Sponsors are encouraged to develop processes and procedures to contact the facility in the least burdensome manner to request assistance from the facility to identify beneficiaries who are not cognitively impaired and may be able to accept the offer to participate in their CMR, and beneficiaries who have a health care proxy. In the event that the definition of authorized representative differs by State or in settings other than LTC, we defer to State law.

The change we are proposing to the regulatory text reflects longstanding CMS guidance and is also consistent with the discussion of this policy in the preamble to the April 2012 final rule (77 FR 22140). Plan sponsors have complied with this policy for several years as evidenced by CMS data analyses using plan-reported data to identify contract-level outliers regarding CMR completion rates, the CMR recipient, and cognitive impairment status of MTM program enrollees. As such, there is no associated paperwork burden not already accounted for and approved by the Office of Management and Budget under OMB control number 0938–1154 (CMS–10396).

3. Requirement For In-Person or Synchronous Telehealth Consultation

Since 2011, the regulation at § 423.153(d)(1)(vii)(B)(*1*)(*i*) has required that CMRs provided under a Part D sponsor's MTM program include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. In the preamble to both the proposed (74 FR 54693) and final rules (75 FR 19773) in which we first adopted this requirement, CMS emphasized that the consultation must be conducted in real-time, either face-to-face or via an alternative real-time method, such as the telephone. We further specified in response to public comments that plans would have the discretion to determine the method used, including emerging technologies, as long as the CMR is conducted in real-time. In MTM guidance issued annually through Call Letters and HPMS memoranda, most recently in the April 30, 2021 HPMS memorandum titled, ''Correction to CY 2022 MTM Program Guidance and Submission Instructions,'' CMS has specified that CMRs should be performed in real-time.

In the 12 years since we finalized the current regulation text, including during the COVID–19 public health emergency, telehealth capabilities have developed considerably and experienced significant growth. In its Best Practice Guide: Telehealth for Direct-To-Consumer Care (*https://telehealth.hhs.gov/providers/direct-to-consumer/*), HHS refers to synchronous telehealth as an interaction that occurs in live, real-time settings, usually via phone or video. Asynchronous telehealth, also referred to as ''store-and-forward,'' involves communication that is sent and received at different times (for example, a patient sends photos to their doctor that the doctor reviews later). Advancements in telehealth, such as widespread use of smart phones and secure video interactions, have confounded the concept of ''person-to-person'' interaction, which CMS—in the context of the current CMR requirements in § 423.153(d)(1)(vii)(B)(1)(i)—intended to refer to an in-person interaction as opposed to a telehealth consultation.

As a result of these developments, CMS has identified a need to update our regulatory text. We propose to amend

the existing regulation text at § 423.153(d)(1)(vii)(B)(1)(i) to require that the CMR be performed either in person or via synchronous telehealth to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth. While the consultation must be conducted in real-time, under this proposal, plans would continue to have the discretion to determine whether the CMR can be performed in person or using the telephone, video conferencing, or another real-time method.

The change proposed in this section is consistent with our longstanding policy that the CMR be conducted in real-time as described in the original rulemaking establishing the CMR requirement and codifies existing guidance, issued annually, which plan sponsors have complied with for years. Sponsors are required to submit their MTM program parameters to CMS for review each year, and, in doing so, are required to indicate the type of interactive, person-to-person or telehealth consultation (for example, face-to-face, telephone, telehealth), and to supply a detailed description of the CMR consultation. Because this proposed change codifies existing program guidance with which plans are already compliant, there is no paperwork burden associated with it.

4. MTM Program Technical Changes

We are proposing several technical changes to the regulation text related to the Part D MTM program. At § 423.4, we propose to add a definition for ''MTM program'' to clarify the meaning of this term as used in Part 423. In the heading for § 423.153(d), we propose to remove the dash and replace it with a period to be consistent with other paragraph headings in Subpart D. We propose to amend § 423.153(d) by striking ''or'' from the end of existing paragraph (d)(2)(i)(C)(2) to clarify that, consistent with section 1860D–4(c)(2)(A)(ii) of the Act, plan sponsors must target enrollees described in paragraph (d)(2)(i) and enrollees described in paragraph (d)(2)(ii). Throughout Part 423, Subpart D, we propose to replace ''MTMP'' with ''MTM program'' to ensure that the terminology is used consistently.

S. Standards for Electronic Prescribing (§ 423.160)

We propose updates to the standards to be used by Medicare Part D prescription drug plans for electronic prescribing (e-prescribing). This includes: (1) after a transition period, requiring the National Council for Prescription Drug Plans (NDPDP) SCRIPT standard version 2022011 proposed for adoption at 45 CFR 170.205(b), and retiring the current NCPDP SCRIPT standard version 2017071, as the e-prescribing standard for transmitting prescriptions and prescription-related information (including medication history and electronic prior authorization (ePA) transactions) using electronic media for covered Part D drugs for Part D eligible individuals; (2) requiring the NCPDP Real-Time Prescription Benefit (RTPB) standard version 12 proposed for adoption at 45 CFR 170.205(c) as the standard for prescriber real-time benefit tools (RTBTs) supported by Part D sponsors; and (3) revising current regulatory text referring to standards for eligibility transactions.

In this proposed rule, we propose a novel approach to updating e-prescribing standards by cross-referencing Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the standards adopted for electronic transactions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations. A joint approach to adopting and updating electronic prescribing standards aims to mitigate potential compliance challenges for HHS and the healthcare industry that may result from independent adoption of such standards.

The NCPDP SCRIPT standards are used to exchange information between prescribers, dispensers, intermediaries and Medicare prescription drug plans (PDPs). The Medicare Part D statute at section 1860D–4(e) of the Act and regulations at § 423.160(a) require drug plans participating in the prescription benefit to support e-prescribing, as defined at § 423.159(a), and physicians and pharmacies who transmit prescriptions and related communications electronically, to utilize the adopted standards. The proposed updated NCPDP SCRIPT standards have been requested by the industry and provide a number of updates that the industry and CMS support. Accordingly, we propose to update § 423.160 throughout for prescription, medication history, and ePA transactions utilizing the NCPDP SCRIPT standard, as well as to permit an 18-month transition period beginning July 1, 2023 where either NCPDP SCRIPT standard version 2017071 or 2022011 can be used, with exclusive use of NCPDP SCRIPT standard version 2022011 required by January 1, 2025.

The NCPDP RTPB standard enables the exchange of patient eligibility, preferred pharmacy network participation status, product coverage (including any restrictions and alternatives), and associated cost sharing so prescribers have access to this information through a RTBT application that can be utilized at the point-of-prescribing. As discussed in section III.Y.2. of this proposed rule, CMS requires at § 423.160(b)(7) that Part D sponsors implement one or more electronic RTBTs that are capable of integrating with at least one prescriber's electronic prescribing system or electronic health record, as of January 1, 2021; however, at the time CMS established this requirement, no single industry RTPB standard was available. The NCPDP RTPB standard version 12 has since been developed and tested in real-world applications. We propose to require it as the standard for prescriber RTBT applications at § 423.160(b)(7) starting January 1, 2025.

Eligibility transactions utilize the NCPDP Telecommunication or Accredited Standards Committee X12 standard for pharmacy or other health benefits, respectively. The Part D program has adopted standards based on the HIPAA electronic transaction standards, which have not been updated for more than a decade. Pursuant to legal authority that we discuss in this rule, we propose to update the Part D regulation at § 423.160(b)(3) by adding a new paragraph (iii) indicating that eligibility transactions must utilize the applicable standard named in the HIPAA regulation at 45 CFR 162.1202, which we propose to be required beginning July 1, 2023 in 42 CFR 423.160(b)(1)(vi). Since the HIPAA regulation currently identifies the same standards that are named at § 423.160(b)(3)(i) and (ii), we anticipate no immediate impact from this proposed change in regulatory language. However, on November 9, 2022, HHS's proposed rule titled ''Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Adoption of Pharmacy Subrogation Standard,'' (87 FR 67634), which proposes to adopt updated versions of the retail pharmacy standards for electronic transactions at 45 CFR 462.1202, appeared in the **Federal Register**. Thus, our proposal will assure Part D requirements align with the HIPAA requirements should a newer version of the NCPDP Telecommunication (or other) standards be adopted as the HIPAA standard for these types of electronic transactions as

a result of the aforementioned proposed rule and any future HHS rules.

1. Legislative Background

Section 1860D–4(e) of the Act requires the adoption of Part D e-prescribing standards. Part D sponsors are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. For a further discussion of the statutory requirements at section 1860D–4(e) of the Act, refer to the proposed rule titled ''Medicare Program; E-Prescribing and the Prescription Drug Program,'' which appeared in the February 4, 2005 **Federal Register** (70 FR 6255). Section 6062 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), hereinafter referred to as the SUPPORT Act, amended section 1860D–4(e)(2) of the Act to require the adoption of transaction standards for the Part D e-prescribing program to ensure secure ePA request and response transactions between prescribers and Part D plan sponsors for Part D-covered drugs prescribed to Part D-eligible individuals. There is generally no requirement that Part D prescribers or dispensers implement e-prescribing, with the exception of required electronic prescribing of Schedule II, III, IV, and V controlled substances that are Part D drugs, consistent with section 2003 of the SUPPORT Act and as specified at § 423.160(a)(5). However, prescribers and dispensers who electronically transmit and receive prescription and certain other information regarding covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

2. Regulatory History

As specified at § 423.160(a)(1), Part D plan sponsors are required to support the Part D e-prescribing program transaction standards. Likewise, as specified at § 423.160(a)(2), providers and pharmacies that conduct electronic transactions for covered Part D drugs for Part D eligible individuals for which a program standard has been adopted must do so using the adopted standard. Transaction standards are periodically updated to take new knowledge, technology, and other considerations into account. As CMS adopted specific versions of the standards when it initially adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the industry. CMS discussed these processes in the final rule titled ''Medicare Program; E-Prescribing and the Prescription Drug Program,'' which appeared in the November 7, 2005 **Federal Register** (70 FR 67579). An account of successive adoption of new and retirement of previous versions of various e-prescribing standards is described in the final rule titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014,'' which appeared in the December 10, 2013 **Federal Register** (78 FR 74229); the proposed rule titled ''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,'' which appeared in the November 28, 2017 **Federal Register** (82 FR 56336); and the corresponding final rule (83 FR 16440), which appeared in the April 16, 2018 **Federal Register**. The final rule titled ''Medicare Program; Secure Electronic Prior Authorization For Medicare Part D,'' which appeared in the December 31, 2020 **Federal Register** (85 FR 86824), codified the requirement that Part D sponsors support the use of NCPDP SCRIPT standard version 2017071 for certain ePA transactions (85 FR 86832).

The final rule titled ''Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses,'' which appeared in the May 23, 2019 **Federal Register** (84 FR 23832), codified at § 423.160(b)(7) the requirement that Part D sponsors adopt an electronic RTBT capable of integrating with at least one prescriber's electronic prescribing or electronic health record (EHR) system, but did not name a standard since no industry standard was available at the time. The electronic standards for eligibility transactions were codified in the final rule titled ''Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,'' which appeared in the May 16, 2012 **Federal Register** (77 FR 29001), to align with the applicable HIPAA standards.

The Part D program has historically adopted electronic prescribing standards independently of other HHS components that may adopt electronic prescribing standards under separate authorities; however, past experience has demonstrated that duplicative adoption of health IT standards by other agencies within HHS under separate authorities can create significant burden on industry as well as HHS when those standards impact the same technology systems. Notably, independent adoption of the NCPDP SCRIPT standard version 2017071 by CMS at § 423.160 (83 FR 16638) in 2018, which required use of the standard beginning in 2020, led to a period where ONC had to exercise special enforcement discretion in its Health Information Technology (IT) Certification Program until the same version was incorporated into regulation at 45 CFR 170.205(b)(1) through the final rule titled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,'' which appeared in the May 1, 2020 **Federal Register** (85 FR 25679). This resulted in significant impact on both ONC and CMS program resources in order to address stakeholder concerns about misalignment. See section III.T. of this proposed rule for additional discussion of ONC's proposal and authority. Similarly, the preamble of the May 2012 final rule noted that, in instances in which an e-prescribing standard has also been adopted as a HIPAA transaction standard in 45 CFR part 162, the process for updating the e-prescribing standard would have to be coordinated with the maintenance and modification of the applicable HIPAA transaction standard (77 FR 29018).

3. Adoption of NCPDP SCRIPT Standard Version 2022011 as the Part D Electronic Prescribing Standard, Retirement of NCPDP SCRIPT Standard Version 2017071, and Related Conforming Changes in § 423.160

The NCPDP SCRIPT standard has been the adopted electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals since foundation standards were named in the final rule titled ''Medicare Program; E-Prescribing and the Prescription Drug Program,'' which appeared in the November 7, 2005 **Federal Register** (70 FR 67568), at the start of the Part D program. The NCPDP SCRIPT standard is used to exchange information between prescribers, dispensers, intermediaries and Medicare prescription drug plans. In addition to electronic prescribing, the NCPDP SCRIPT standard is used in electronic prior authorization (ePA) and medication history transactions.

Although electronic prescribing is optional for physicians, except as to Schedule II, III, IV, and V controlled substances that are Part D drugs prescribed under Part D, and

pharmacies, the Medicare Part D statute and regulations require drug plans participating in the prescription benefit to support electronic prescribing, and physicians and pharmacies who elect to transmit prescriptions and related communications electronically must utilize the adopted standards except in limited circumstances.

NCPDP requested that CMS adopt the proposed updated NCPDP SCRIPT standard version 2022011 in a letter to CMS dated January 14, 2022.[132] The updated version provides a number of updates that the industry and CMS support. A major enhancement includes functionality that supports a 3-way transaction among prescriber, facility, and pharmacy, which will enable electronic prescribing of controlled substances in the long-term care (LTC) setting (for which compliance actions will commence on or after January 1, 2025 as specified in § 423.160(a)(5)). Additional major enhancements include general extensibility, redesign of the Product/Drug groupings, Observation elements added to REMS transaction, ProhibitRenewalRequest added to RxChangeResponse and RxRenewalResponse, modified Structured and Codified Sig Structure format, and data element refinements and support related to dental procedure codes, RxBarCode, PatientConditions, patient gender and pronouns, TherapeuticSubstitutionIndicator, and multi-party communications and withdrawal/retracting of a previous sent message using the MessageIndicatorFlag.

Because the functionality offered in NCPDP SCRIPT standard version 2022011 offers important updates and efficiencies to the healthcare industry, we believe it would be an appropriate electronic prescribing standard for the Medicare Part D program. NCPDP SCRIPT standard version 2022011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071. This allows for a less burdensome implementation process and flexible adoption timeline for the industry since backwards compatibility permits a transition period where both versions of the NCPDP SCRIPT standards may be used simultaneously.

In addition to its use for electronic prescriptions, the NCPDP SCRIPT standard is used for medication history (§ 423.160(b)(4)) and ePA transactions (§ 423.160(b)(8)). Thus, we propose conforming amendments to require, after a transition period, NCPDP SCRIPT standard version 2022011 as the Part D electronic prescribing standard for the medication history transactions and ePA transactions in § 423.160(b)(4) and § 423.160(b)(8), respectively.

Instead of independently naming the NCPDP SCRIPT standard version 2022011 and incorporating the corresponding implementation guide by reference at § 423.160(c), we propose to amend § 423.160(b) throughout by cross referencing 45 CFR 170.205(b), where ONC proposes to adopt NCPDP SCRIPT standard version 2022011. See section III.T.5. of this proposed rule for additional discussion of this coordination effort. We propose the same approach for the amendments listed at § 423.160(b)(2) for prescription transactions, discussed in this section of this proposed rule, and conforming changes at § 423.160(b)(4) for medication history transactions and at § 423.160(b)(8) for ePA transactions.

The proposed approach would enable CMS and ONC to avoid misalignment from independent adoption of NCPDP SCRIPT standard version 2022011 for their respective programs. Updates to the standard would impact requirements for both programs at the same time, ensure consistency, and promote alignment for providers, payers, and health IT developers participating in and supporting the same prescription transactions.

Since the NCPDP SCRIPT standard version 2022011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071, the industry can accommodate a transition period when either version may be used. We propose changes at §§ 423.160(b)(1)(vi), 423.160(b)(4)(iii), and 423.160(b)(8)(iii), which, taken together with ONC proposals for 45 CFR 170.205(b), would establish a transition period from July 1, 2023 until January 1, 2025, with a compliance deadline of January 1, 2025, when use of NCPDP SCRIPT standard version 2022011 will be mandatory. Given NCPDP SCRIPT standard version 2022011 is backwards compatible with NCPDP SCRIPT standard version 2017071, we are seeking to allow Part D plans to begin updating to NCPDP SCRIPT standard version 2022011 as soon as practicable. While we are proposing July 1, 2023 for the start of the transition period, we will consider updating the proposed start date for the transition period in the final rule to align with the effective date for the final rule if it falls before July 1, 2023.

In its letter to CMS requesting CMS to adopt NCPDP SCRIPT standard version 2022011, NCPDP requested that CMS identify certain transactions for prescriptions for which use of the standard is mandatory. The transactions for prescriptions that we propose to codify at § 423.160(b)(2)(v)(A)–(Y) are:

- GetMessage;
- Status;
- Error;
- NewRxRequest;
- NewRx;
- RxChangeRequest;
- RxChangeResponse;
- RxRenewalRequest;
- Resupply;
- RxRenewalResponse;
- Verify;
- CancelRx;
- CancelRxResponse;
- RxFill;
- DrugAdministration;
- NewRxResponseDenied;
- RxTransferInitiationRequest (previously named RxTransferRequest in NCPDP SCRIPT standard version 2017071);
- RxTransfer (previously named RxTransferResponse NCPDP SCRIPT standard version 2017071);
- RxTransferConfirm;
- RxFillIndicatorChange;
- Recertification;
- REMSIinitiationRequest;
- REMSIinitiationResponse;
- REMSRequest; and
- REMSResponse.

The transactions for ePA that we propose to codify at § 423.160(b)(8)(iii)(A)–(I) are:

- PAInitiationRequest;
- PAInitiationResponse;
- PARequest;
- PAResponse;
- PAAppealRequest;
- PAAppealResponse;
- PACancelRequest;
- PACancelResponse; and
- PANotification.

The transactions specific to electronic prescribing remain the same as those required for NCPDP SCRIPT standard version 2017071 (§ 423.160(b)(2)(iv)), except where renamed as noted above. The transactions specific to ePA are also the same as those required with NCPDP SCRIPT standard version 2017071, with one additional transaction (PANotification) which was incorporated into the standard after NCPDP SCRIPT standard version 2017071. As discussed in section III.T.6. of this proposed rule, NCPDP SCRIPT standard version 2022011 is proposed for adoption at 45 CFR 170.205(b)(2), and SCRIPT version 2017071 is proposed to expire on January 1, 2025 at 45 CFR 170.205(b)(1). Consequently, use of NCPDP SCRIPT standard version 2022011 for the transactions related to electronic prescribing and ePA (proposed at §§ 423.160(b)(2)(v)(A)–(Y) and 423.160(b)(8)(iii)(A)–(I),

[132] *https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf.*

respectively) will be mandatory by January 1, 2025, if the expiration date for SCRIPT version 2017071 is adopted as proposed. We also note that the RxTransfer-related transactions take place between pharmacies (that is, dispensers) and are not applicable to prescribers. Therefore, we have proposed to acknowledge this in the proposed regulation at § 423.160(b)(2)(v) by adding language that indicates that the business functions supported by the transactions listed for the transmission of prescription-related information may be between prescribers and dispensers (as stated in § 423.160(b)(2)(iv)) or between dispensers.

Mandatory use of the NCPDP SCRIPT standard for the transactions listed means that the specified version of the NCPDP SCRIPT standard must be used to carry out the particular business function supported by the transaction. Mandatory use does not mean that all transactions must be utilized (that is, if the business function supported by the transaction is not needed, then the NCPDP SCRIPT standard transaction would not be utilized). For example, we have been informed that the ''GetMessage'' transaction is not widely used among prescribers. For this reason, we are reiterating guidance [133] that the NCPDP SCRIPT standard transactions named are not themselves mandatory, but rather they are to be used as applicable to the entities specified at § 423.160(a) involved in completing or supporting such business functions when and if they are utilized. Our intent is that the applicable NCPDP SCRIPT standard version is used for business functions that the applicable NCPDP SCRIPT standard transactions support, which are named in regulation. We believe the pharmacy industry has implemented the standards in this manner, based on discussions with NCPDP. However, we acknowledge that the transactions currently named in regulation, and as we propose, are specific to the NCPDP SCRIPT standard. Thus, the specific transactions (based on literal interpretation) can only be used in the context of the NCPDP SCRIPT standard as a whole. We propose to add language at §§ 423.160(b)(2)(v) and 423.160(b)(8)(iii) to indicate that these transactions represent the business functions for which the NCPDP SCRIPT standard transactions must be used if such business function is utilized.

In summary, we propose to amend § 423.160 by:

- Revising paragraph § 423.160(b)(1)(v) to reference applicable standards for transactions until June 30, 2023;
- Adding paragraph § 423.160(b)(1)(vi) to identify applicable standards for transactions beginning July 1, 2023;
- Adding paragraph § 423.160(b)(2)(v) to acknowledge the entities to whom certain transactions are applicable, to include distinction that the transactions listed represent business functions for which the NCPDP SCRIPT standard must be used, and to indicate that communication of prescriptions and prescription-related transactions listed at § 423.160(b)(2)(v)(A)–(Y) must comply with 45 CFR 170.205(b). This cross-reference permits a transition period when either NCPDP SCRIPT standard versions 2017071 or 2022011 may be used because, as ONC has proposed at 45 CFR 170.205(b)(1), the NCPDP SCRIPT standard version 2017071 would not expire until January 1, 2025;
- Revising paragraph § 423.160(b)(4)(ii) to indicate exclusive use of NCPDP SCRIPT standard version 2017071 for medication history transactions is required from January 1, 2020 until June 30, 2023;
- Adding paragraph § 423.160(b)(4)(iii) indicating that starting July 1, 2023, medication history transactions must comply with 45 CFR 170.205(b). This cross-reference would permit a transition period when either NCPDP SCRIPT standard versions 2017071 or 2022011 may be used to complete medication history transactions because ONC proposes at 45 CFR 170.205(b)(1) that the NCPDP SCRIPT standard version 2017071 would not expire until January 1, 2025;
- Revising paragraph § 423.160(b)(8)(ii) to indicate exclusive use of NCPDP SCRIPT standard version 2017071 for ePA transactions is required from January 1, 2022 until June 30, 2023; and
- Adding paragraph § 423.160(b)(8)(iii) indicating that starting July 1, 2023, ePA transactions listed at § 423.160(b)(8)(iii)(A)–(I) represent business functions which must comply with 45 CFR 170.205(b). This cross-reference would permit a transition period when either NCPDP SCRIPT standard versions 2017071 or 2022011 may be used for ePA transactions because ONC proposes at 45 CFR 170.205(b)(1) that the NCPDP SCRIPT standard version 2017071 would not expire until January 1, 2025.

We specifically solicit comment on the following aspects of this proposal: (1) requiring NCPDP SCRIPT version 2022011 and retiring NCPDP SCRIPT standard version 2017071, following a transition period; (2) requiring compliance with 45 CFR 170.205(b) to align Part D electronic prescribing requirements with standards adopted by ONC; and (3) whether the proposed date of January 1, 2025 to retire NCPDP SCRIPT standard version 201071 provides a sufficient transition period for industry and other interested stakeholders or if delaying this date to January 1, 2026 or later offers advantages or disadvantages.

4. Adoption of the NCPDP Real-Time Prescription Benefit (RTPB) Standard

In the May 2019 final rule (84 FR 23832), which implemented the statutory provision at section 1860D–4(e)(2)(D) of the Act, CMS required at § 423.160(b)(7) that Part D plan sponsors implement, by January 1, 2021, an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's e-prescribing system or electronic health record (EHR) to provide prescribers with complete, accurate, timely and clinically appropriate patient-specific real-time formulary and benefit information (including out-of-pocket cost, clinically appropriate formulary alternatives, and utilization management requirements). At that time, there were no industry-wide standards for RTBTs. NCPDP has since developed and tested an RTPB standard for use with RTBT applications. In an August 20, 2021 letter to CMS, NCPDP recommended adoption of RTPB standard version 12.[134] The NCPDP RTPB standard version 12 enables the real-time exchange of information about patient eligibility, patient-specific formulary and benefit information, and preferred pharmacy network participation status. For a submitted drug product, the RTPB standard will indicate coverage status, coverage restrictions, and patient financial responsibility. The RTPB standard also supports providing information on alternative pharmacies and products.

The NCPDP RTPB standard version 12 standard is designed for prescriber, not beneficiary, RTBT applications; however, CMS is aware that the use of the NCPDP RTPB standard for the prescriber RTBT may facilitate beneficiary RTBTs since the data elements from the NCPDP RTPB standard would also be able to feed into a beneficiary RTBT. CMS is not

[133] Supporting Electronic Prescribing Under Medicare Part D. September 19, 2008. *https://www.hhs.gov/guidance/document/supporting-electronic-prescribing-under-medicare-part-d.*

[134] *https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBandFandBStandardsAdoptionRequest.pdf.*

prohibiting such a practice, but we emphasize that we are not proposing that the proposed standard be required for beneficiary RTBTs. The requirements for the beneficiary RTBT are discussed in the final rule titled ''Medicare and Medicaid Programs; Contract Year 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,'' which appeared in the January 19, 2021 **Federal Register** (86 FR 5864).

As discussed in section III.T.6. of this proposed rule, ONC proposes to adopt the NCPDP RTPB standard version 12 at 45 CFR 170.205(c). We therefore propose to add paragraphs § 423.160(b)(1)(vii) and § 423.160(b)(7)(i) to indicate that as of January 1, 2025, Part D sponsors' RTBT must comply with 45 CFR 170.205(c).

We solicit comment on this proposal.

5. Standards for Eligibility Transactions

We propose to revise § 423.160(b)(3) by adding a new paragraph (iii) to indicate that eligibility transactions must comply with 45 CFR 162.1202. Both sections currently name the NCPDP Telecommunication standard Version D.0 with equivalent batch standard Version 1.2 and the Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 5010 (ASC X12N/005010x279). The eligibility standards adopted at § 423.160(b)(3)(i) and (ii) were adopted to align with those adopted at 45 CFR 162.1202, pursuant to the final rule titled ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act HIPAA) Electronic Transaction Standards,'' which appeared in the January 16, 2009 **Federal Register** (74 FR 3326). The proposed rule titled ''Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Adoption of Pharmacy Subrogation Standard,'' which appeared in the November 9, 2022 **Federal Register** (87 FR 67634), proposes to update the HIPAA standards used for eligibility transactions. We therefore propose to streamline the Part D regulation by indicate that eligibility transactions must comply with the applicable HIPAA regulations, as opposed to naming standards independently, which would ensure, should the HIPAA standards be updated as a result of HHS rulemaking, that the Part D regulation would be synchronized with the required HIPAA standards. We foresee no immediate impact of this proposed change since the HIPAA regulation at 45 CFR 162.1202 currently identifies the same standards as those named in the Part D regulation at § 423.160(b)(3)(i) and (ii), but we believe establishing a cross-reference would help avoid potential future conflicts so that the industry and CMS would not be at risk of compliance issues.

Thus, we propose to modify § 423.160(b)(3) by adding a new paragraph (iii) to indicate that eligibility transactions should comply with 45 CFR 162.1202. We also propose to replace earlier references to § 423.160(b)(3) in paragraphs § 423.160(b)(1)(i) through (b)(1)(iv) with revised references to § 423.160(b)(3)(i) and (ii), to specify where these historical standards referred to the standards specifically named at § 423.160(b)(3)(i) and (ii). This approach would avoid ambiguity with respect to historical expectations from prior to April 1, 2009 through the proposed effective date of July 1, 2023, which we propose in § 423.160(b)(1)(vi).

We solicit comment on this proposal.

T. Adoption of Health IT Standards (45 CFR 170.205)

1. Overview

In this section ONC proposes to adopt standards for electronic prescribing and related activities on behalf of HHS under the authority in Section 3004 of the Public Health Service Act (42 U.S.C. 300jj–14). ONC is proposing these standards for adoption by HHS as part of a nationwide health information technology infrastructure that supports reducing burden and health care costs and improving patient care. ONC is proposing to adopt these standards on behalf of HHS in one location within the Code of Federal Regulations for HHS use, including by the Part D Program as proposed in section III.S. of this proposed rule. These proposals reflect a unified approach across the Department to adopt standards for electronic prescribing activities that have previously been adopted separately by CMS and ONC under independent authorities. This new approach is intended to increase alignment across HHS and reduce regulatory burden for stakeholders subject to program requirements that incorporate these standards.

2. Statutory Authority

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created ''Title XXX—Health Information Technology and Quality'' (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health IT and exchange of electronic health information (EHI). Subsequently, Title IV of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) amended portions of the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

3. Adoption of Standards and Implementation Specifications

Section 3001 of the PHSA directs the National Coordinator for Health Information Technology (National Coordinator) to perform duties in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information. Section 3001(b) of the PHSA establishes a series of core goals for development of a nationwide health information technology infrastructure that—

- Ensures that each patient's health information is secure and protected, in accordance with applicable law;
- Improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;
- Reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;
- Provides appropriate information to help guide medical decisions at the time and place of care;
- Ensures the inclusion of meaningful public input in such development of such infrastructure;
- Improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;
- Improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;
- Facilitates health and clinical research and health care quality;

• Promotes early detection, prevention, and management of chronic diseases;
• Promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and
• Improves efforts to reduce health disparities.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria, and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1) of the PHSA, the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) of the PHSA and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, which is titled ''Subsequent Standards Activity,'' provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the Health IT Advisory Committee (HITAC). As noted in the final rule, ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' (ONC 2015 Edition Final Rule), which appeared in the October 16, 2015 **Federal Register**, we consider this provision in the broader context of the HITECH Act and the Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria (80 FR 62606).

Under the authority outlined in section 3004(b)(3) of the PHSA, the Secretary may adopt standards, implementation specifications, and certification criteria as necessary even if those standards have not been recommended and endorsed through the process established for the HITAC under section 3002(b)(2) and (3) of the PHSA. Moreover, while HHS has traditionally adopted standards and implementation specifications at the same time as adopting certification criteria that reference those standards, the Secretary's authority under section 3004(b)(3) of the PHSA is not limited to adopting standards or implementation specifications at the same time certification criteria are adopted.

Finally, the Cures Act amended the PHSA by adding section 3004(c), which specifies that in adopting and implementing standards under section 3004, the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.

4. Alignment With Federal Advisory Committee Activities

The HITECH Act established two Federal advisory committees, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC). Each was responsible for advising the National Coordinator on different aspects of health IT policy, standards, implementation specifications, and certification criteria.

Section 4003(e) of the Cures Act amended section 3002 of the PHSA and replaced the HITPC and HITSC with one committee, the HITAC. After that change, section 3002(a) of the PHSA establishes that the HITAC advises and recommends to the National Coordinator standards, implementation specifications, and certification criteria relating to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. The Cures Act specifically directed the HITAC to advise on two areas: (1) A policy framework to advance an interoperable health information technology infrastructure (section 3002(b)(1) of the PHSA); and (2) priority target areas for standards, implementation specifications, and certification criteria (section 3002(b)(2) of the PHSA).

For the policy framework, as described in section 3002(b)(1)(A) of the PHSA, the Cures Act tasked the HITAC with providing recommendations to the National Coordinator on a policy framework for adoption by the Secretary consistent with the Federal Health IT Strategic Plan under section 3001(c)(3) of the PHSA. In February of 2018, the HITAC made recommendations to the National Coordinator for the initial policy framework [135] and subsequently published a schedule in the **Federal Register** and an annual report on the work of the HITAC and ONC to implement and evolve that framework.[136] For the priority target areas for standards, implementation specifications, and certification criteria, section 3002(b)(2)(A) of the PHSA identified that in general, the HITAC would recommend to the National Coordinator, for purposes of adoption under section 3004 of the PHSA, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. In October of 2019, the HITAC finalized recommendations on priority target areas for standards, implementation specifications, and certification criteria.[137]

5. Aligned Approach to Standards Adoption

Historically, the ONC Health IT Certification Program and the Part D Program have maintained complementary policies of aligning health IT certification criteria and associated standards related to electronic prescribing, medication history, and electronic prior authorization for prescriptions. Prescribers of Medicare Part D covered drugs that are prescribed for a Medicare Part D eligible individual must generally adhere to the standards set by the Part D Program for conveying prescriptions using electronic media, while participants in the Promoting Interoperability programs must use technology certified under ONC's Health IT Certification Program to complete measures included in the program, including e-prescribing. Alignment across the standards adopted for these HHS programs is critical to ensure consistent regulatory requirements for Part D plan sponsors, health care providers, and health IT developers who implement and utilize technology tools for electronic prescribing. In addition to adopting the same standards, ONC and CMS must

[135] HITAC Policy Framework Recommendations, February 21, 2018: *https://www.healthit.gov/sites/default/files/page/2019-07/2018-02-21_HITAC_Policy-Framework_FINAL_508-signed.pdf.*

[136] HITAC Annual Report CY 2019 published March 2, 2020: *https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf.*

[137] HITAC recommendations on priority target areas, October 16, 2019: *https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf.*

also align the requirements for use of those standards within their respective programs.

In this section of this proposed rule, we briefly summarize past standards adoption activities under section 3004 of the PHSA intended to ensure alignment for electronic prescribing and related activities across the ONC Health IT Certification Program and the Part D Program.

On January 13, 2010, the Secretary issued an interim final rule ''Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology'' (2010 interim final rule) which adopted an initial set of standards, implementation specifications, and certification criteria to meet the requirement specified at section 3004(b)(1) of the PHSA (75 FR 2013). To ensure consistency with standards previously adopted by CMS under the MMA for electronic prescribing, the 2010 interim final rule adopted NCPDP SCRIPT standard version 8.1 by referencing the Part D requirement for use of the standard in § 423.160. The 2010 interim final rule also adopted the Formulary and Benefits standard version 1.0 (75 FR 2031) for the purposes of performing a drug formulary check by referencing the Part D requirement for use of the standard in § 423.160.

On July 28, 2010, ONC's final rule ''Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology'' to complete the adoption of an initial set of standards, implementation specifications, and certification criteria, appeared in the **Federal Register** (75 FR 44589). In that final rule, ONC replaced the reference to § 423.160 adopted in the 2010 interim final rule, as previously described, by adopting and incorporating by reference both NCPDP SCRIPT standard version 8.1 and NCPDP SCRIPT standard version 10.6 in 45 CFR 170.205. As stated in the final rule, ONC finalized this policy to align with the adoption and incorporation by reference of NCPDP SCRIPT standard version 10.6 by CMS in the ''Medicare Program; Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (NCPDP SCRIPT 10.6)'' interim final rule, which appeared in the July 1, 2010 **Federal Register** (75 FR 38026).

Most recently, in the ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (ONC 21st Century Cures Act Final Rule), which was effective June 30, 2020, ONC adopted NCPDP SCRIPT standard version 2017071 in 45 CFR 170.205(b)(1) and incorporated it by reference in 45 CFR 170.299 (85 FR 25678). By adopting this standard, ONC aligned with 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 (2019 Part C/D final rule), which appeared in the April 16, 2018 **Federal Register**, in which CMS adopted and incorporated NCPDP SCRIPT standard version 2017071 in § 423.160(b)(2)(iv) for use beginning in January 2020 (83 FR 16440).

While CMS and ONC have worked closely together to ensure consistent adoption of standards through regulatory actions, as previously described, we recognize that the current practice of different HHS components conducting parallel adoption of the same standards may result in additional regulatory burden and confusion for stakeholders. As a result of different HHS components maintaining and updating separate regulatory provisions in different areas of the Code of Federal Regulations for health IT standards that impact the same stakeholders, impacted stakeholders must monitor changes to standards in multiple regulatory vehicles. In addition, ONC and CMS must identify separate regulatory vehicles and pursue separate rulemaking processes in which to adopt the same standard. Due to other constraints around regulatory cycles in each agency, proposed and final actions to adopt the same standard may occur on different timelines. For instance, due to discrepancies between regulatory timelines, adoption of the NCPDP SCRIPT standard version 2017071 in different rules (respectively, the ONC 21st Century Cures Act final rule and the 2019 Part C/D final rule) led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program.[138] Stakeholders affected by these updates expressed repeated concerns during this period regarding when updates to respective standards would be finalized and how these regulatory contingencies would affect program requirements referencing these standards.

Given past concerns, ONC and CMS are seeking to pursue a new approach to alignment of standards in this proposed rule. Under this approach, HHS would adopt the standards specified (the NCPDP SCRIPT standard version 2022011 and the NCPDP Real-Time Prescription Benefit standard version 12) under the Secretary's authority to adopt health IT standards in the PHSA. If finalized, these proposals would result in the adoption and incorporation by reference to the proposed standards in a single Code of Federal Regulations location at 45 CFR 170.205. Programs across HHS could then cross-reference the adopted standards. As more than one version of the NCPDP SCRIPT standard would be specified in 45 CFR 170.205(b) if our proposal is finalized, we have also identified an expiration date for the current version of the standard to clearly specify when versions of the NCPDP SCRIPT standard in 45 CFR 170.205(b) would be available for use by HHS programs.

We note that these proposals pertain only to the adoption and incorporation by reference of the proposed standards, and when these standards are available for use by HHS. CMS and ONC would continue to set other program requirements independently for programs such as the ONC Health IT Certification Program and the Part D Program, which may require use of these standards. For instance, program requirements may continue to include provisions such as additional amendments or guidance related to use of standards specific to each program. However, we believe that the approach reflected in these proposals for adoption of standards in a single CFR location for HHS use will help to address the concerns around alignment, as previously described. We are requesting comment on this approach to adopting standards in a single location for HHS use.

6. Proposal To Adopt Standards for Use by HHS

Consistent with section 3004(b)(3) of the PHSA and the efforts, as previously described, to evaluate and identify standards for adoption, we propose to adopt the following implementation specifications in 45 CFR 170.205(b)(2) and (c), on behalf of the Secretary, to support the continued development of a nationwide health information technology infrastructure as described under section 3001(b) of the PHSA, and to support Federal alignment of standards for interoperability and health information exchange. Specifically, we

[138] See the archived version of the Certification Companion Guide for the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3): *https://www.healthit.gov/sites/default/files/page/2020-12/b3_ccg.pdf.*

propose to adopt the following standards:

- NCPDP SCRIPT Standard, Implementation Guide, Version 2022011.
- NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12.

a. Electronic Prescribing

As discussed previously, ONC has previously adopted three versions of the NCPDP SCRIPT standard in 45 CFR 170.205. Most recently, we adopted NCPDP SCRIPT standard version 2017071 in the ONC 21st Century Cures Act final rule to facilitate the transfer of prescription data among pharmacies, prescribers, and payers (85 FR 25678).

The updated NCPDP SCRIPT standard version 2022011 includes important enhancements, such as additions for drug utilization review/use (DUR/DUE) alerts and formulary information, as well as transactions to relay medication history and for a facility to notify a pharmacy of resident information. Enhancements have been added to support electronic prior authorization functions as well as electronic transfer of prescriptions between pharmacies.[139]

We propose to remove NCPDP SCRIPT standard version 10.6 from 45 CFR 170.205(b)(2) and to adopt NCPDP SCRIPT standard version 2022011 [140] in 45 CFR 170.205(b)(2). We note that NCPDP SCRIPT standard version 10.6 is no longer required for use in either the Part D Program or the ONC Health IT Certification Program, and we believe it is appropriate to remove this standard from the Code of Federal Regulations. We also propose to incorporate NCPDP SCRIPT standard version 2022011 by reference in 45 CFR 170.299.

Regarding the NCPDP SCRIPT standard version 2017071, we propose to revise the regulatory text in 45 CFR 170.205(b)(1) to specify that adoption of this standard will expire on January 1, 2025. If these proposals are finalized, this would mean that both the 2017071 and 2022011 versions of the NCPDP SCRIPT standard would be available for HHS use from the effective date of a final rule until January 1, 2025. This ''transition period'' is consistent with previous policy in both the ONC Health IT Certification Program and the Part D program with respect to versions of e-prescribing standards which allow for concurrent usage. On and after January 1, 2025, only the 2022011 version of the NCPDP SCRIPT standard would be available for HHS use where a standard in 45 CFR 170.205(b) is required.

We request comment on the appropriateness of this proposed expiration date for NCPDP SCRIPT standard version 2017071, and whether we should consider, as an alternative, finalizing a transition period of an additional year, up to January 1, 2026, or a longer period. We are interested in whether commenters believe an extended transition period, during which use of both standards would be allowed for programs requiring use of a standard in 45 CFR 170.205(b), would be appropriate. We welcome any information commenters can provide about the time needed for stakeholders to implement the updated version of the standard for different uses.

While we are not proposing changes to the ''electronic prescribing'' certification criterion in the ONC Health IT Certification Program (45 CFR 170.315(b)(3)) in this proposed rule, ONC will consider any updates to this criterion in future rulemaking to align with the updated NCPDP SCRIPT standard and with the Part D program, should this proposal be finalized, consistent with past practice.

b. Real Time Prescription Benefit

We propose to adopt the NCPDP Real-Time Prescription Benefit standard version 12 to meet the requirements of Division CC, Title I, Subtitle B, Section 119 of the Consolidated Appropriations Act, 2021 (CAA), Public Law 116–260. The CAA required sponsors of Medicare prescription drug plans and Medicare Advantage Organizations to implement a real-time benefit tool that meets technical standards named by the Secretary, in consultation with ONC. The NCPDP Real-Time Prescription Benefit standard version 12 [141] enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions and alternatives when they exist.

In section III.S. of this proposed rule, CMS is proposing to require Part D plan sponsors to comply with this standard when implementing the real-time benefit tool or tools required in § 423.160(b)(7). In addition, section 119(b) of the CAA amended the definition of a ''qualified electronic health record'' in section 3000(13) of the PHSA to specify that a ''qualified electronic health record'' must include or be capable of including a real-time benefit tool. ONC intends to address this provision in future rulemaking for the ONC Health IT Certification Program and will ensure alignment with the proposed NCPDP Real-Time Prescription Benefit standard version 12, should our proposal be finalized, and related proposals in the Part D program where appropriate.

We also note that the HITAC has previously addressed real-time prescription benefit standards, consistent with its statutory role to recommend standards. In 2019, the HITAC accepted the recommendations included in the 2018 report of the Interoperability Priorities Task Force, including recommendations to continue to monitor standards then being developed for real-time prescription benefit transactions, and, when the standards are sufficiently validated, to require EHR vendors to provide functionality that integrates real time patient-specific prescription benefit checking into the prescribing workflow.[142] In early 2020, the National Committee on Vital and Health Statistics (NCVHS) and HITAC convened another task force, the Intersection of Clinical and Administrative Data (ICAD) Task Force, which was charged with convening industry experts and producing recommendations related to electronic prior authorizations. The task force report was presented to HITAC in November 2020 [143] and discussed the NCPDP Real-Time Prescription Benefit standard as an important tool for addressing administrative transactions around prescribing.

We are proposing to adopt the NCPDP Real-Time Prescription Benefit standard version 12 [144] in 45 CFR 170.205(c)(1) and to incorporate this standard by reference in 45 CFR 170.299. As noted in section III.S.4. of this proposed rule, CMS proposes at § 423.160(b)(7)(i) to require this standard for use by Part D plan sponsors to fulfill the requirements for real-time benefit tools at § 423.160(b)(7). As previously noted, ONC will consider proposals to require use of this standard to support real-time benefit tool functionality in the ONC Health IT Certification Program, consistent with Section 119 of the CAA, in future rulemaking.

We solicit comment on these proposals.

[139] See *https://standards.ncpdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf.*

[140] See *http://www.ncpdp.org/Standards/Standards-Info.*

[141] See *http://www.ncpdp.org/Standards/Standards-Info.*

[142] See *https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf.*

[143] See *https://www.healthit.gov/sites/default/files/page/2020-11/2020-11-17_ICAD_TF_FINAL_Report_HITAC.pdf.*

[144] See *http://www.ncpdp.org/Standards/Standards-Info.*

c. Interoperability Standards Advisory

ONC's Interoperability Standards Advisory (ISA) supports the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the health care industry to address specific interoperability needs.[145] The ISA is updated on an annual basis based on recommendations received from public comments and subject matter expert feedback. This public comment process reflects ongoing dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be used to address a specific interoperability need.

ONC currently identifies the standards proposed for adoption in this section within the ISA as available standards for a variety of potential use cases. The NCPDP SCRIPT standard version 2022011 and the NCPDP Real-Time Prescription Benefit standard version 12 are currently identified under the ''Pharmacy Interoperability'' domain.[146] We encourage interested parties to review the ISA to better understand key applications for the implementation specifications proposed for adoption in this proposed rule.

7. ONC Health IT Certification Program

As previously noted, we are not proposing new or revised certification criteria based on the proposed adoption of standards within this rulemaking. Regarding the Real-Time Prescription Benefit Standard, Section 119 of the CAA does not require ONC to adopt certification criteria for RTBT at the same time as the standard, but instead allows that the criteria be established after the standard has been adopted by HHS. We are therefore proposing to adopt the standard for HHS use and, as previously discussed, ONC would address new or revised certification criteria referencing the standard, if finalized, in separate rulemaking. We believe this will not only support alignment across HHS, but will allow for continued input from interested parties on how this standard should be incorporated into specific certification criteria for certified health IT functionality prior to any such proposals in future rulemaking. ONC will continue to collaborate with CMS to ensure that any future proposals in the ONC Health IT Certification Program continue to advance alignment with program requirements under the Part D Program.

We believe the approach reflected in the standards proposals in this proposed rule will support Federal alignment and coordination of Federal activities with adopted standards and implementation specifications for a wide range of systems, use cases, and data types within the broad scope of health information exchange. Historically, State, Federal, and local partners have leveraged the standards adopted by ONC on behalf of HHS to inform program requirements, technical requirements for grants and funding opportunities, and systems implementation for health information exchange. We believe the adoption of these standards will support HHS partners in setting technical requirements and advancing the use of innovative health IT solutions for electronic prescribing and related activities.

U. Incorporation by Reference (45 CFR 170.299)

The Office of the Federal Register has established requirements for materials (for example, standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5(a)). Specifically, 1 CFR 51.5(a) requires agencies to discuss, in the preamble of a proposed rule, the ways that the materials it proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties; and summarize, in the preamble of the proposed rule, the material it proposes to incorporate by reference.

To make the materials we intend to incorporate by reference reasonably available, we provide a uniform resource locator (URL) for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URLs provided. In instances where they are not directly available, we note the steps and requirements necessary to gain access to the standard or implementation specification. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization. In certain instances, where noted, access requires a fee or paid membership. As an alternative, a copy of the standards may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201. Please call (202) 690–7171 in advance to arrange inspection.

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. We have followed the NTTAA and OMB Circular A–119 in proposing standards and implementation specifications for adoption, and note that the technical standards proposed for adoption in 45 CFR 170.205 in this proposed rule were developed by NCPDP, which is an ANSI-accredited, not-for-profit membership organization using a consensus-based process for standards development.

As required by 1 CFR 51.5(a), we provide summaries of the standards we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations. We also provide relevant information about these standards and implementation specifications in the preamble where these standards are proposed for adoption.

- National Council for Prescription Drug Programs (NCPDP), SCRIPT Standard Implementation Guide, Version 2022011, January 2022 (Approval Date for ANSI: December 2, 2021)

URL: *http://www.ncpdp.org/Standards/Standards-Info.*

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

Summary: NCPDP SCRIPT is a standard created to facilitate the transfer of prescription data between pharmacies, prescribers, and payers. The current standard supports transactions regarding new prescriptions, prescription changes, renewal requests, prescription fill status notification, and prescription cancellation. Enhancements have been

[145] See *https://www.healthit.gov/isa.*

[146] See *https://www.healthit.gov/isa/section/pharmacyinteroperability.*

added for drug utilization review/use (DUR/DUE) alerts and formulary information as well as transactions to relay medication history and for a facility to notify a pharmacy of resident information. Enhancements have been added to support electronic prior authorization functions as well as electronic transfer of prescriptions between pharmacies.

- National Council for Prescription Drug Programs (NCPDP), Real-Time Prescription Benefit Standard, Implementation Guide, Version 12, October 2021 (Approval Date for ANSI: September 27, 2021)

URL: *http://www.ncpdp.org/Standards/Standards-Info.*

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

Summary: The NCPDP Real-Time Prescription Benefit Standard Implementation Guide is intended to meet the industry need within the pharmacy services sector to facilitate the ability for pharmacy benefit payers/processors to communicate to providers and to ensure a consistent implementation of the standard throughout the industry. The Real-Time Prescription Benefit (RTPB) Standard enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions, and alternatives when they exist.

V. Limitation on PDP Contracts Held by Subsidiaries of the Same Parent (§ 423.272)

1. Overview and Summary

We are proposing to limit the number of PDP contracts under which a Part D sponsor or its parent organization (as defined in § 423.4), directly or through subsidiaries, can offer individual market PBPs in a PDP region to one contract per region. Individual market PBPs are plans that are marketed to all Medicare beneficiaries in a region, unlike employer group waiver plans, which are only open to retirees whose employers contract with them to provide Part D benefits. This requirement would promote longstanding CMS policy to encourage meaningful competition among and a level playing field for Part D sponsors in the Part D program. The policy to promote meaningful competition has been implemented through our crosswalk policy (discussed in section IV.AD. of this proposed rule), the limit of three per region on the number of PDP plan benefit packages (PBP) that a sponsor can offer (codified effective January 1, 2022 at current § 423.265(b)(2)), the requirement that PDP PBPs offered by a sponsor be ''substantially different'' (codified effective January 1, 2011 at § 423.272(b)(3)), and the prohibition on approval of applications that would result in a sponsor or its parent holding more than one PDP contract per region (codified effective July 22, 2014 at § 423.503(a)(3)).

2. Discussion

Since the beginning of the Part D program, CMS has promoted meaningful competition among Part D sponsors and meaningful choice among plans for Part D beneficiaries. CMS has pursued multiple avenues to promote these goals. CMS attempts to ensure that PDP sponsors only offer the number and type of PBPs necessary to provide beneficiaries meaningfully different plan options. Effective January 1, 2022, we codified at § 423.265(b) our longstanding policy limiting the number of PBPs a PDP sponsor may offer to no more than three in a service area. These offerings may not include more than one PBP offering basic prescription drug coverage, as defined at § 423.100, and no more than two enhanced alternative plans, as defined at § 423.104(f)(1). The enhanced plan offerings must be ''substantially different'' from the basic prescription drug coverage pursuant to § 423.272(b)(3). All three PBPs are usually offered under the same contract, although if a sponsor or its parent holds multiple contracts, the sponsor may only operate three PBPs across all the contracts in the region. CMS allows Part D sponsors, or the parent organizations of Part D sponsors, a two-year transition period to meet these requirements after they have acquired another Part D sponsor pursuant to § 423.272(b)(3)(ii). Finally, under § 423.503(a)(3), CMS does not approve an application to qualify as a PDP sponsor that would result in the applicant's parent organization, directly or through subsidiaries, holding more than one PDP sponsor contract offering individual market plans in a PDP region.

Consistent with these requirements, CMS has traditionally encouraged PDP sponsors and their parent organizations that acquire new PDP contracts by, for example, merging with or acquiring other PDP sponsors to consolidate their PDP contracts so that they only offer individual market PBPs under one PDP contract per PDP region. Individual market PBPs are plans that are marketed to all Medicare beneficiaries in a region, unlike employer group waiver plans, which are only open to retirees whose employers contract with them to provide Part D benefits. Such contract consolidations are accomplished through contract consolidation crosswalks, described in section IV.AD. of this proposed rule, which allow sponsors to transfer enrollment from a non-renewing PDP to the surviving PDP.

CMS advises that plans take not more than two full benefit years to accomplish a consolidation. CMS uses its negotiation authority under section 1860D–11(d)(2)(B) of the Act, the three-plan limit, and the substantial difference requirement to encourage consolidations. Both the three-plan limit and the substantial difference requirements are applied at the parent organization level—that is, a parent organization with subsidiaries that hold multiple contracts in a PDP region cannot, after the two-year transition period following acquisition, offer more than three PDP PBPs in that region. PDP sponsors usually consolidate their PDPs in response to our encouragement and to accommodate the three-plan limit and substantial difference requirements, but some have delayed consolidation or declined to consolidate altogether. In proposing to require consolidations, CMS intends not only to promote meaningful choice and competition, but to ensure a level playing field for all affected PDP sponsors.

At § 423.272(b), we propose to add a new paragraph (5) to codify limits on the number of PDP contracts held by subsidiaries of the same parent organization in a PDP region. We propose to adopt this requirement pursuant to our authority to add additional contract terms and conditions, not inconsistent with Part C, as necessary and appropriate (see section 1860D–12(b)(3)(D) of the Act). We propose to add a new paragraph (5)(i) to provide that CMS would no longer approve bids that would result in a PDP sponsor or a PDP sponsor's parent organization, directly or through its subsidiaries, offering individual market PBPs under more than one PDP contract in a PDP region. This proposed requirement would not apply to EGWP PBPs. For instance, if Parent Organization 1 had two subsidiaries, Sponsor 1 and Sponsor 2, that each had a PDP contract in Region 3 for at least the past two years, CMS would not approve the bids from both Sponsor 1 and Sponsor 2 unless one of the contracts was non-renewed or its service area reduced so it no longer served Region 3. This requirement would align bid review and approval criteria with our current prohibition at § 423.503(a)(3) on approving applications that would result in

multiple PDPs held by the same sponsor or parent organization in a region.

This proposal promotes meaningful competition among Part D sponsors by preventing sponsors that are controlled and operated by the same parent organization from offering competing PDP contracts in a region. Two subsidiaries of the same parent organizations offering plans in the same PDP region are not truly competitors, as decisions concerning their operations are ultimately controlled by a single entity or parent organization. PDP sponsors under common parent organizations usually share leadership and operational staff, use the same pharmacy benefit manager, and use the same systems and procedures to administer the Part D benefit across different contracts. Because of § 423.503(a)(3), the only way a parent organization could have two PDP sponsor contracts in a region is if they applied for them before we adopted § 423.503(a)(3) in 2014 or if they purchase an existing PDP sponsor. CMS does not believe that it is fair to continue to allow these exceptions to our general policy limiting the number of contracts that a parent organization may operate in a region.

CMS is also concerned that Part D sponsors and parent organizations offering multiple PDPs in a region may do so to segment risk or manipulate Part D Star Ratings. Informal communications with organizations seeking multiple contracts in a region have indicated that some of these organizations wish to segregate low-income beneficiaries into their own contract and/or confine the experience of a low performing plan to a single contract. Allowing organizations to isolate low income, or otherwise high risk or high cost, individuals into a single contract subverts Part D nondiscrimination requirements at section 1860D–11(e)(2)(D)(i) of the Act. Allowing segregation of low performing plans in a different contract from higher performing plans offered by a subsidiary of the same parent organization also undermines the integrity of CMS's Star Ratings. CMS assigns star ratings at the contract level. Ratings are meant to reflect all aspects of the PDP operations controlled by a contracting entity. This purpose is undermined when a parent organization is allowed to effectively administer two or more PDP contracts in a region in a way that would allow them to inflate their Star Ratings under one of the contracts by confining poor-performing plans to another contract. Such manipulation of the Star Ratings could mislead beneficiaries about the performance of the organization responsible for administering a plan.

CMS recognizes that consolidating contracts held by subsidiaries of the same parent organization can be complex and requires careful planning, particularly if one or more of these contracts was recently acquired through the purchase of or merger with another PDP sponsor. Consistent with CMS's current practice, CMS is therefore proposing at new paragraphs (5)(ii) and (iii) to allow sponsors or parent organizations that acquire new PDP contracts or that operate more than one contract in a PDP region as of January 1, 2024 a transition period of two bid cycles to reduce the number of PDP contracts offering individual market PBPs to one per region. This proposed requirement would not apply to EGWP PBPs, so that subsidiaries of a parent organization could continue to operate multiple PDP contracts in a region so long as all but one of those contracts only operated EGWP PBPs in that region.

Consolidating PDP contracts results in the beneficiaries from one contract being transferred, or ''crosswalked,'' into a PBP in another contract held by a subsidiary of the same parent organization. We are proposing to codify this process at section IV.AD. of this proposed rule. Consolidations can involve substantial disruption to operations and affected enrollees' experience. Particularly where a newly acquired PDP contract is served by a different pharmacy benefit manager, sponsors must plan carefully to update systems and transfer information in a way that minimizes disruptions for beneficiaries. Benefits can also vary significantly between PBPs offered under different PDP contracts immediately following an acquisition. Based on its experience in the program, CMS has found that a transition period of two bid cycles is sufficient for plans to minimize disruptions by planning for transitions and, where appropriate, gradually adjusting the benefits offered by PBPs under different contracts each year so that benefit structures between two contracts are more closely aligned before beneficiaries are crosswalked to a different contract.

Consistent with current practice when encouraging consolidations and assessing substantial difference under § 423.272(b)(3), CMS would only apply the proposed limit on PDP contracts after the sponsor or its parent has submitted bids under multiple contracts for two contract years. For example, if a parent organization currently operates Contract 1 in a region and acquires Contract 2 in the same region on September 1, 2024, the organization would be permitted to operate multiple contracts for the remainder of 2024 and for 2025, as well as for 2026 and 2027. The parent organization would not have had the opportunity to adjust the 2025 bid in light of the acquisition because it did not acquire the contract until after the 2025 bid deadline. CMS would therefore allow them to submit bids for 2026 and 2027 in 2025 and 2026, respectively, in order to plan for an orderly transition.

CMS acknowledges that a few Part D sponsors and parent organizations have operated multiple PDP contracts offering individual market PBPs in a region for many years. For the reasons already discussed, CMS does not believe that this is consistent with our policy promoting meaningful competition and beneficiary choices. Nor do we believe that allowing parent organizations whose contracts predate the 2014 restriction on approval of applications that would result in multiple PDP contracts to continue to operate multiple contracts in region is fair to other parent organizations. CMS also believes that continuing to allow these sponsors to operate multiple contracts in a region is unfair to organizations that may be required to reduce the number of contracts offered in a region following an acquisition pursuant to the proposed provisions at § 423.272(b)(5)(i) and (ii). CMS therefore proposes to require these parent organizations to reduce the number of PDPs offered in a region to one PDP per parent, per region, after a transition period of two bid cycles as described previously. For example, if this proposed rule is finalized prior to the 2024 bid submission deadline of June 5, 2023, a parent organization holding two or more PDP contracts at that time (directly or through subsidiaries) would be allowed to submit 2024 and 2025 bids for multiple contracts in 2023 and 2024, but would be required to submit 2026 bids in 2025 that only included one PDP per region.

CMS solicits comments on the length of the transition period proposed at paragraph (b)(5)(iii). In particular, CMS solicits comments on whether the transition periods for new acquisitions and organizations offering multiple PDP contracts on January 1, 2024 should be the different to account for the fact that organizations offering multiple PDP contracts on January 1, 2024 do not face the same transition difficulties as organizations that acquire new PDP contracts.

In summary, we are proposing to:

- Add § 423.272(b)(5) to limit the number of PDP contracts held by subsidiaries of the same parent

organization to one PDP contract per region;

• At proposed § 423.272(b)(5)(ii) & (iii), provide a two-year transition period for parent organizations that do not currently meet the requirement or that violate the requirement following a future acquisition to comply with the requirement.

We solicit comment on these proposals.

W. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c), (§ 401.305(a)(2))

Section 6402(a) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act) established section 1128J(d) of the Act. Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, and to notify the Secretary, State, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(4)(B) of the Act defines the term ''overpayment'' as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. Section 1128J(d)(4)(C) of the Act defines, the term ''person'' for purposes of Medicare Part A and Part B to include providers and suppliers as those terms are defined in the Act. Section 1128J(d)(4)(C) of the Act also defines the term ''person'' for purposes of Medicare Part C and Part D to include a Medicare Advantage organization (''MAO'') (as defined in section 1859(a)(1) of the Act) and a Part D sponsor (as defined in section 1860D–41(a)(13) of the Act).

Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation (as defined in 31 U.S.C. 3729(b)(3)) for purposes of the False Claims Act, 31 U.S.C. 3729.

Section 1128J(d)(4)(A) of the Act provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). The False Claims Act (31 U.S.C. 3729(b)(1)(A)) defines the terms ''knowing'' and ''knowingly'' to include information about which a person ''has actual knowledge,'' ''acts in deliberate ignorance of the truth or falsity of the information,'' or ''acts in reckless disregard of the truth or falsity of the information.''

1. Regulations Promulgated Under Section 1128J(d) of the Act

The agency has published two final rules under section 1128J(d) of the Act. On May 23, 2014, CMS published a final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29844) (hereinafter referred to as the final ''Parts C & D Overpayment Rule''), which provided, among other things, that an MAO or Part D sponsor has identified an overpayment when the MAO or Part D sponsor has determined, or should have determined through the exercise of reasonable diligence, that the MAO or Part D sponsor has received an overpayment.

On February 12, 2016, we published a final rule titled ''Medicare Program; Reporting and Returning of Overpayments, in Medicare Parts A and B'' (81 FR 7654) (hereinafter referred to as the final ''Parts A & B Overpayment Rule''), which provided, among other things, that a provider or supplier has identified an overpayment when the provider or supplier has determined, or should have determined through the exercise of reasonable diligence, that the provider or supplier has received an overpayment and quantified the amount of the overpayment.

2. Relevant Litigation

In *UnitedHealthcare Insurance Co.* v. *Azar,* a group of MAOs challenged the final Parts C & D Overpayment Rule, and the District Court held, in relevant part, that by requiring MAOs to use ''reasonable diligence'' in searching for and identifying overpayments, the final rule impermissibly created False Claims Act liability for mere negligence. *UnitedHealthcare Ins. Co.* v. *Azar,* 330 F. Supp. 3d 173, 191 (D.D.C. 2018), rev'd in part on other grounds sub nom. *UnitedHealthcare Ins. Co.* v. *Becerra,* 16 F.4th 867 (D.C. Cir. 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21–1140). The District Court noted that ''(t)he False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. 1320a–7k(d)(3)—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly' . . . a term of art defined in the FCA to include false information about which a person 'has actual knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' '' *Id.* at 190. We now propose to amend the final Parts C & D Overpayment Rule at §§ 422.326(c) and 423.360(c), as well as the final Parts A & B Overpayment Rule at § 401.305(a)(2), to remove the reference to ''reasonable diligence'' and replace it with language at section 1128J(d)(4)(A) that gives the terms ''knowing'' and ''knowingly'' the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). *See UnitedHealthcare,* 330 F. Supp. 3d at 191 (finding that this language would be consistent with a 2000 agency rule, the FCA, and the Affordable Care Act's reference to the FCA).

3. Provisions of Proposed Regulations

a. Medicare Part A and Part B—Amending the Standard for When an Overpayment Is Identified (§ 401.305(a)(2))

This section of the proposed rule would amend § 401.305(a)(2) to change the standard for an ''identified overpayment.'' Consistent with the proposed Medicare Part C and Part D provisions under this Overpayment Rule, we propose to remove the existing standard and adopt, by reference, the False Claims Act definition of ''knowing'' and ''knowingly.'' Under the proposed rule, a provider or supplier has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

b. Medicare Advantage Program and Part D—Amending the Standard for When an Overpayment Is Identified (§§ 422.326(c) and 423.360(c))

This section of the proposed rule would amend §§ 422.326(c) and 423.360(c) to change the standard for an ''identified overpayment'' to align with the statutory obligation provided by Congress in section 1128J(d)(4)(A) of the Act, which provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). We propose to remove the existing standard and adopt, by reference, the False Claims Act definition of ''knowing'' and ''knowingly.'' Under the proposed rule, an MA organization or Part D sponsor has identified an overpayment if it has actual knowledge

of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

A. Amending the Definition of Severe or Disabling Chronic Condition; Defining C–SNPs and Plan Types; and Codifying List of Chronic Conditions (§ 422.2)

A specialized MA plan for special needs individuals, generally known as a special needs plan or SNP, is an MA plan specifically designed to provide targeted care and limit enrollment to special needs individuals. CMS defines Specialized MA Plans for Special Needs Individuals at § 422.2 as an MA coordinated care plan (CCP) that exclusively enrolls special needs individuals as set forth in § 422.4(a)(1)(iv) and that provides Part D benefits under part 423 to all enrollees; and which has been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population. As provided in section 1859(b)(6) of the Act and the definition in § 422.2, a special needs individual could be any one of the following: an institutionalized or institutionalized-equivalent individual; a dual eligible individual; or an individual with a severe or disabling chronic condition and who would benefit from enrollment in a specialized MA plan. Chronic Condition Special Needs Plans (C–SNPs) are SNPs that restrict enrollment to special needs individuals with specific severe or disabling chronic conditions, defined at § 422.2.

The Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1859 of the Act to revise the definition of ''severe or disabling chronic condition'' for purposes of identifying individuals eligible to enroll in C–SNPs beginning January 1, 2022; add care management requirements for special needs individuals who have a severe or disabling chronic condition; direct the Secretary to convene a panel of clinical advisors to establish and update a list of severe or disabling chronic conditions that meet certain criteria; mandate the inclusion of several current C–SNP chronic conditions onto the list; and direct that the panel take into account the availability of benefits in the Medicare Advantage Value-Based Insurance Design model. Section 1859(f)(9) of the Act, as added by the BBA, instructs the Secretary to convene the panel of clinical advisors not later than December 31, 2020 and every 5 years thereafter, to establish and update a list of conditions that meet the statutory criteria to be a severe or disabling chronic condition and conditions that meet the statutory criteria for certain other conditions that require prescription drugs, providers, and models of care that are unique to the specific populations covered by MA special needs plans. We are proposing to codify the BBA of 2018's amendment of the definition of severe or disabling chronic condition; define C–SNP; update and codify the recommended list of chronic conditions by a panel of clinical advisors as specified by the BBA; and codify existing subregulatory guidance permitting the inclusion of certain chronic condition combinations for the purposes of offering single standalone C–SNP plan benefit packages (PBPs).

1. Amending the Definition of Severe or Disabling Chronic Condition

Section 231 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended sections 1851(a)(2)(A) and 1859(b) of the Act to authorize the creation of specialized MA plans for special needs individuals, including specialized MA plans that exclusively enroll individuals with severe or disabling chronic conditions. The MMA did not define severe and disabling chronic conditions but noted that the Secretary may determine specific requirements that special needs individuals would need to meet in order to enroll in a chronic condition plan. In the proposed rule titled, ''Medicare Program; Establishment of the Medicare Advantage Program'' (69 FR 46865), which appeared in the August 3, 2004 issue of the **Federal Register** (hereinafter, the August 2004 MA proposed rule), CMS did not propose a definition of ''severe or disabling chronic condition''; however, we asked for comments on whether CMS should set standards for the designation of an individual with severe or disabling chronic conditions and what criteria should be used. In the ensuing final rule titled Medicare Program: Establishment of the Medicare Advantage Program (70 FR 4588), which appeared in **Federal Register** on the January 28, 2005 (hereinafter the January 2005 MA final rule), we declined to establish a detailed definition of severe and disabling chronic because of concerns that a definition might limit plan flexibility. The January 2005 MA final rule stated that CMS would review and evaluate proposals for specialized MA plans that serve beneficiaries who may qualify for enrollment in SNPs covering severe or disabling chronic disease categories, and that among the criteria to be considered would be the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against ''sicker'' members of the target population (70 FR 4596). CMS then developed a process that allowed MA organizations to identify qualifying chronic conditions.

Section 164(e) of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) added a new clause to section 1859(b)(6)(B)(iii) of the Act to clarify the definition of the special needs individuals eligible for C–SNPs. Beginning on January 1, 2010, the third type of special needs individual (in addition to the categories for individuals who were institutionalized or dually eligible for Medicare and Medicaid) was defined as an individual who has one or more co-morbid and medically complex chronic condition(s) that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care. CMS continued to use the term ''special needs individual who has a severe or disabling chronic condition'' for this group. Based on the MIPPA amendments to the Act, CMS adopted the definition of severe or disabling chronic condition at § 422.2 in the final rule with comment period titled Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions, which appeared in the **Federal Register** on January 12, 2009 (74 FR 1493, hereafter, the January 2009 final rule (FR)). (The January 2009 FC discussed and finalized a number of provisions related to eligibility for and performance requirements for C–SNPs and SNPs generally.)

Section 164(e) of MIPPA also directed the Secretary to convene a panel of clinical advisors to determine the chronic conditions that meet the definition severe or disabling chronic conditions used in the amendment to the definition at section 1859(b)(6)(B)(iii) of the Act. CMS subsequently convened the panel in October 2008 and implemented the fifteen SNP-specific chronic conditions recommended by the panel that met the

definition of severe or disabling and needed specialized care management. The list was later incorporated into Chapter 16b of the Medicare Managed Care Manual (MMCM).

In 2018, the BBA of 2018 amended section 1859(b)(6)(B)(iii) of the Act by adding a new definition of special needs individuals to apply beginning January 1, 2022. Under the new definition of special needs individual, an eligible individual must, on or after January 1, 2022, ''have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination and that is listed under [section 1859(f)(9)(A) of the Act].'' Subsection (f)(9)(A) directs the Secretary to convene a panel of clinical advisors every 5 years to review and revise a list of chronic conditions that meet two sets of criteria:

- The amended definition of a severe or disabling chronic condition in subsection (b)(6)(B)(iii); and
- Conditions that require prescription drugs, providers, and models of care that are unique to the specific population of enrollees in a specialized MA plan for special needs individuals and either (1) as a result of enrollment in a C–SNP, the enrollee with the condition would have a reasonable expectation of meeting a certain standard regarding health status, outcomes and costs compared to other coverage options, or (2) the condition has a low prevalence in the general population of Medicare beneficiaries or a disproportionally high per-beneficiary cost.

We are proposing now to amend the definition of severe or disabling chronic condition at § 422.2 to match the definition at section 1859(b)(6)(B)(iii)(II) of the Act and to include the specific conditions identified by the panel convened under section 1859(f)(9)(A) of the Act.

Currently, CMS provides guidance on severe or disabling chronic conditions that meet the current regulatory definition of the term in Chapter 16b of the Medicare Managed Care Manual (MMCM), which includes a list of SNP-specific chronic conditions in section 20.1.2. That list of conditions was drawn from a panel of clinical advisors established under section 164(e)(2) of the MIPPA of 2008. Starting in 2010, CMS adopted subregulatory guidance whereby a C–SNP could only offer a plan benefit package (PBP) that covered one of the fifteen SNP-specific chronic conditions identified in the guidance. Several of the chronic condition categories include a list of sub conditions that provide further information regarding the types of diseases that qualify under the chronic condition categories. Examples of such conditions include autoimmune disorders, cardiovascular disorders, severe hematologic disorders, chronic lung disorders, chronic disabling mental health conditions, and chronic disabling neurologic disorders. A C–SNP that targets several sub-categorical disorders must enroll an eligible beneficiary who has one or more of these sub-categorical disorders; the C–SNP is not permitted to exclude an eligible beneficiary having the covered condition or a covered sub-categorical condition. For example, a C–SNP that enrolls special needs individuals with a chronic and disabling mental health condition must enroll special needs individuals with one or more of the following sub-categorical conditions: bipolar disorders, major depressive disorder, paranoid disorder, schizophrenia, or schizoaffective disorder. Currently, C–SNPs may only cover one of the fifteen qualifying chronic conditions in a single PBP, unless the C–SNP receives approval from CMS to focus on a group of severe or disabling chronic conditions. Generally, CMS believes that structuring a C–SNP to target multiple commonly co-morbid conditions that are not clinically linked in their treatment would result in a general market product rather than an MA plan that is sufficiently tailored for special needs individuals. Therefore, CMS will approve targeting of multiple severe or disabling chronic conditions by a C–SNP only for: (1) one of the CMS-developed group of commonly co-morbid and clinically linked conditions listed in section 20.1.3.1 of Chapter 16b where the special needs individuals may have one or more of the conditions in the grouping or (2) a MAO-customized group of multiple co-morbid and clinically linked conditions where the special needs individuals served by the C–SNP have all of the specified conditions.

In meeting its obligation under section 1859(f)(9)(A) of the Act to convene a panel of clinical advisors not later than December 31, 2020, to establish the list of conditions that meet the statutory criteria, CMS was committed to engaging the public—industry, advocates, beneficiaries, and medical professional societies—in the discussion about appropriate SNP-specific chronic conditions. Panel members were tasked with assessing the statutory criteria for reviewing the appropriateness of potential conditions as required by section 1859(f)(9)(A) of the Act. The criteria are:

- The condition meets the definition of a severe or disabling chronic condition under section 1859(b)(6)(B)(iii)(II) of the Act on or after January 1, 2022; and
- Conditions that require prescription drugs, providers, and models of care that are unique to the special needs individuals with several or disabling chronic conditions as defined in subsection (b)(6)(B)(iii)(II) of section 1859 of the Act as of that date and:

++ As a result of access to, and enrollment in, such a specialized MA plan for special needs individuals, individuals with such condition would have a reasonable expectation of slowing or halting the progression of the disease, improving health outcomes and decreasing overall costs for individuals diagnosed with such condition compared to available options of care other than through such a specialized MA plan for special needs individuals; or

++ Have a low prevalence in the general population of beneficiaries under this title or a disproportionally high per-beneficiary cost under title XVIII of the Act. In addition, sections 1859(f)(9)(B) and (C) of the Act require that:

- The list of severe or disabling chronic conditions used for C–SNPs include: HIV/AIDS, end stage renal disease (ESRD), and chronic and disabling mental illness.
- The panel consider the availability of varied benefits, cost-sharing, and supplemental benefits under the Medicare Advantage Value-Based Insurance Design (VBID) model being tested by the Center for Medicare and Medicaid Innovation (CMMI).

On August 8, 2019, CMS announced a Request for Information (RFI) related to the review of C–SNP specific chronic conditions as mandated by the BBA of 2018 to solicit comments from the public to assist the panel of advisors convened by CMS under section 1859(f)(9)(A) of the Act.[147] The 2019 SNP Chronic Condition Panel met for three sessions between September 9 and September 23, 2019. CMS provided panelists with a summary of comments received in response to the RFI. The panelists reviewed and discussed the written public comments from 14 stakeholders representing the industry, advocacy groups, medical societies, and beneficiaries. The panelists also

[147] The full RFI can be found here: *https://www.cms.gov/Medicare/Health-Plans/SpecialNeedsPlans/Downloads/RFI-Chronic-Condition-SNP-Panel.pdf.*

examined the chronic conditions already covered by existing C–SNPs. They employed their collective national and international experience with chronic condition research and clinical practice to weigh inclusion of chronic conditions on the list. As in 2008, the panelists also considered the condition's prevalence in the Medicare population, a factor that would potentially affect the capacity of an MA organization to attract eligible enrollees and be viable in a given service area as well as being identified in section 1959(f)(9)(A)(ii)(II) of the Act as a criterion to be considered. The panelists were sensitive to the reality that C–SNPs require sufficient disease prevalence and access to a specialized provider network within a marketable service area to manage risk under a capitated payment system (even with risk-adjustment of those capitated payments), and effectively and efficiently serve the targeted special needs beneficiaries. The panelists also reflected on the need for beneficiaries, health care practitioners, and the health care industry to recognize the SNP-specific chronic conditions and consider them appropriate for a specialized service delivery system in order to stimulate participation. While the Panel did consider a condition's prevalence in the Medicare population as required by section 1859(f)(9)(A) of the Act, it was not charged with and did not make any additional judgments based on business considerations (that is, the potential profitability of the selected chronic conditions) as CMS expects interested MA organizations to reach their own conclusions about product offerings and markets in which they wish to operate.

Upon review and deliberation, the Panel identified 22 chronic conditions as meeting the statutory criteria. The conditions identified are:

1. Chronic alcohol use disorder and other substance use disorders;
2. Autoimmune disorders:
- Polyarteritis nodosa,
- Polymyalgia rheumatica,
- Polymyositis,
- Dermatomyositis
- Rheumatoid arthritis,
- Systemic lupus erythematosus,
- Psoriatic arthritis, and
- Scleroderma;

3. Cancer;
4. Cardiovascular disorders:
- Cardiac arrhythmias,
- Coronary artery disease,
- Peripheral vascular disease, and
- Valvular heart disease;

5. Chronic heart failure;
6. Dementia;
7. Diabetes mellitus;
8. Overweight, Obesity, and Metabolic Syndrome;
9. Chronic gastrointestinal disease:
- Chronic liver disease,
- Non-alcoholic fatty liver disease (NAFLD),
- Hepatitis B,
- Hepatitis C,
- Pancreatitis,
- Irritable bowel syndrome, and
- Inflammatory bowel disease;

10. Chronic kidney disease (CKD):
- CKD requiring dialysis/End-stage renal disease (ESRD), and
- CKD not requiring dialysis;

11. Severe hematologic disorders:
- Aplastic anemia,
- Hemophilia,
- Immune thrombocytopenic purpura,
- Myelodysplastic syndrome,
- Sickle-cell disease (excluding sickle-cell trait), and
- Chronic venous thromboembolic disorder;

12. HIV/AIDS;
13. Chronic lung disorders:
- Asthma,
- Chronic bronchitis,
- Cystic Fibrosis,
- Emphysema,
- Pulmonary fibrosis,
- Pulmonary hypertension, and
- Chronic Obstructive Pulmonary Disease (COPD);

14. Chronic and disabling mental health conditions:
- Bipolar disorders,
- Major depressive disorders,
- Paranoid disorder,
- Schizophrenia,
- Schizoaffective disorder,
- Post-traumatic stress disorder (PTSD),
- Eating Disorders, and
- Anxiety disorders;

15. Neurologic disorders:
- Amyotrophic lateral sclerosis (ALS),
- Epilepsy,
- Extensive paralysis (that is, hemiplegia, quadriplegia, paraplegia, monoplegia),
- Huntington's disease,
- Multiple sclerosis,
- Parkinson's disease,
- Polyneuropathy,
- Fibromyalgia,
- Chronic fatigue syndrome,
- Spinal cord injuries,
- Spinal stenosis, and
- Stroke-related neurologic deficit;

16. Stroke;
17. Post-organ transplantation care;
18. Immunodeficiency and Immunosuppressive disorders;
19. Conditions that may cause cognitive impairment:
- Alzheimer's disease,
- Intellectual and developmental disabilities,
- Traumatic brain injuries,
- Disabling mental illness associated with cognitive impairment, and
- Mild cognitive impairment;

20. Conditions that may cause similar functional challenges and require similar services:
- Spinal cord injuries,
- Paralysis,
- Limb loss,
- Stroke, and
- Arthritis;

21. Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell;
22. Conditions that require continued therapy services in order for individuals to maintain or retain functioning.

The Panel recommended a number of changes to the list of chronic conditions that are currently used by CMS to approve C–SNPs. In this proposed rule, we are proposing to codify the list of chronic conditions created by the panel as part of the definition of severe and disabling chronic condition at § 422.2. This proposal takes into account the changes recommended by the panel, as discussed in this section of this proposed rule. These changes include:

- Removed the term ''limited.'' The panel chose this revision so that unlisted chronic conditions will not disqualify the enrollee from plan eligibility even if the unlisted or another listed condition is not the targeted condition that qualifies the beneficiary for a specific C–SNP. In other words, the beneficiary could have other conditions beyond the index condition (which is required to be present) and still be permitted to enroll in a specific C–SNP. For example, a beneficiary with heart failure could also have psoriasis or epilepsy and not be excluded from the Chronic Heart Failure C–SNP. Because our proposal does not exclude a beneficiary from being a special needs individual or eligibility for an applicable C–SNP if the beneficiary has conditions in addition to a severe or disabling chronic condition, we are not proposing to use the word ''including'' in the proposed definition; our proposal is to codify the list of specific conditions (and subconditions) that have been identified as meeting the statutory criteria and avoid ambiguity regarding related but unlisted conditions;
- Renamed ''Chronic alcohol and other drug dependence'' to ''Chronic alcohol use disorder and other substance use disorders;''
- Added dermatomyositis, psoriatic arthritis, and scleroderma to the

Autoimmune disorders chronic condition category;

- The panel recommended changing title of ''Cancer, excluding pre-cancer conditions or in-situ status'' to ''Cancer; ''however; they did not recommend altering the current limitations to the chronic condition category, only a clerical change to the title;
- Added valvular heart disease to the Cardiovascular disorders chronic condition category;
- Added new chronic condition category, ''Overweight, Obesity, and Metabolic Syndrome;''
- Added new chronic condition category, ''Chronic gastrointestinal disease'' with the following conditions: chronic liver disease, non-alcoholic fatty liver disease (NAFLD), hepatitis B, hepatitis C, pancreatitis, irritable bowel syndrome, and inflammatory bowel disease;
- Renamed the ''End Stage Renal Disease (ESRD) requiring dialysis'' condition category to ''Chronic kidney disease (CKD)'' with the following conditions: CKD requiring dialysis/end-stage renal disease (ESRD), and CKD not requiring dialysis;
- Added Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD) to the Chronic lung disorders chronic condition category;
- Added post-traumatic stress disorder (PTSD), eating disorders, and anxiety disorders to the Chronic and disabling mental health conditions category;
- Added fibromyalgia, chronic fatigue syndrome, and spinal cord injuries to the Neurologic disorders conditions category;
- Added post-organ transplantation care and immunodeficiency and immunosuppressive disorders as new chronic condition categories;
- Created new chronic condition category ''Conditions that may cause cognitive impairment,'' including the following sub-conditions: Alzheimer's disease, intellectual disabilities, developmental disabilities, traumatic brain injuries, disabling mental illness associated with cognitive impairment, and mild cognitive impairment;
- Created new chronic condition category ''Conditions that may cause similar functional challenges and require similar services,'' including the following sub-conditions: spinal cord injuries, paralysis, limb loss, stroke, arthritis, and chronic conditions that impair vision, hearing (deafness), taste, touch, and smell; and
- Created new chronic condition category ''Conditions that require continued therapy services in order for individuals to maintain or retain functioning.''

As previously demonstrated in the last three bullets, the panel recommended the creation of several new chronic condition categories that differ from how the current list of severe or disabling chronic conditions uses categories as a single condition or set of related diseases. By including these new categories, we are proposing that C–SNPs will be permitted to create benefit packages and care coordination services to address the needs of beneficiaries who share the same functional needs even if their specific disease or chronic condition may differ. For example, using the condition categories ''Conditions associated with cognitive impairment;'' ''Conditions associated with similar functional challenges and require similar services;'' ''Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell;'' and ''Conditions that require continued therapy services in order for individuals to maintain or retain functioning;'' MA organizations would have the opportunity to propose C–SNPs that seek to ameliorate specific disease outcomes such as impaired vision without having to target one specific chronic condition. In another example, MA organizations would be permitted to create specific care coordination services and benefit packages to address the functional challenges facing beneficiaries with spinal cord injuries and those suffering paralysis from stroke. The challenge for SNPs would be to address the needs not of enrollees who share the same disease or chronic condition, but those diagnosed with different diseases and chronic conditions that share similar impacts on health and functionality. The proposed categories in this paragraph will apply the same statutory and regulatory considerations per the parameters of a severe and disabling chronic condition and as noted in Title XVIII of the Act and part 422. That is, by proposing to list these three categories that are focused on impacts on health and functionality rather than underlying disease or condition, we are not proposing to eliminate the need for the effect on the enrollee to meet the statutory criteria in section 1859(f)(9) of the Act. We believe this new approach to creating a C–SNP is in line with types of services and benefits required of current C–SNPs in operation, and beneficiaries facing similar challenges would benefit from coordination of care among multiple providers for services found in a variety of settings appropriate for the enrollee's health challenges.

Under our proposal, this new definition of severe or disabling chronic condition will be applicable for plan years that begin on or after January 1, 2025. We believe the additional delay will allow plans and CMS to put in the place the necessary operational steps to permit transition between the current list of chronic conditions and the list in this proposal. If adopted in the final rule, several current chronic conditions would transition to new chronic condition categories, such as End Stage Renal Disease (ESRD) and End Stage Liver Disease. As of June 2022, there are 17 ESRD plans with a total enrollment of 4,529 members. There are no C–SNPs that restrict enrollment to End Stage Liver Disease for CY 2022. However, if our proposal is finalized, MA organizations seeking to establish a plan covering End Stage Liver Disease would be able to do so under the proposed new category of Chronic Gastrointestinal Disease. Although this proposal would make changes to the list of conditions used by MA organizations to determine C–SNP plan offerings, we believe the impact of those changes will be minimal. In addition, we are proposing the delay implementing the new chronic condition list in order to give CMS time to collect data and information related to the structuring of the proposed CKD C–SNP plan bids. Per section 1853(a)(1)(H) of the Act, the capitation rates paid to MA plans for enrollees with ESRD are set separately from the capitation rates and bidding benchmarks applicable for other enrollees, which may complicate the transition to using this specific severe or disabling chronic condition category. Current ESRD C–SNPs plan bids are based on a distinct bidding methodology. CMS will provide additional bid pricing information to MAOs if this proposal is finalized. We solicit comment on the proposed updates to this definition. Specifically, we are soliciting comment on our proposal to limit the regulatory definition of severe or disabling chronic condition to the list the conditions on the list established by the panel. Also, we are seeking comment on the proposed list of chronic conditions recommended by the 2019 panel of clinical advisors. We would like to call particular attention to proposed condition numbers 19 through 22. Under these proposed conditions, the C–SNP would focus on specific and clinically appropriate therapeutic approaches that address multiple chronic disease types causing similar

health outcomes and functional limitations. We are seeking feedback on the potential clinical accomplishments that may be addressed through this type of plan design. We are also seeking comment on challenges that might exist both from a clinical and business standpoint. For example, we would be interested to know whether and the extent to which MA organizations require further guidance from CMS to identify chronic conditions or diseases that would fit into condition numbers 19 through 22.

2. Chronic Condition Special Needs Plan Definition, Scope and Eligibility (§§ 422.2, 422.4, and 422.52)

A C–SNP must have specific attributes and meet certain standards that go beyond the provision of basic benefits (as defined in § 422.100(c)) and care coordination that is required of all coordinated care plans; such additional standards include the enrollment limitations and care management requirements set forth in section 1859(f) of the Act and codified in the regulations at §§ 422.52(a) and (b), 422.101(f), and § 422.152(g). While C–SNPs must generally meet requirements that are specified to all SNPs, we believe it is important to codify a definition of C–SNP that reflects how they are limited to serving special needs individuals who have a severe or disabling chronic condition, as defined in § 422.2 (and which we are also proposing to revise). Adopting a definition of C–SNP in § 422.2 would be consistent with how we have previously adopted definitions for the term dual eligible special needs plan (D–SNP) and specific types of D–SNPs. We believe adopting a specific definition will help to clarify how C–SNP specific requirements and policies are distinguishable from requirements and policies for D–SNPs and I–SNPs as well as different from general MA coordinated care plans. Since the intent of the proposed definition is to provide clarification for MA organizations and providers regarding the meaning and scope of C–SNPs, we believe this codification will have little to no impact on MA enrollees nor accrue operational or other costs to MA organizations. Our proposal generally reflects current policy and practice, with a few modifications as discussed where applicable.

As part of current C–SNP subregulatory guidance and during the MA plan application process, MAOs may apply to offer a C–SNP that targets any one of the following:

- A single CMS-approved chronic condition (selected from the list in section 20.1.2 of Chapter 16b);
- A CMS-approved group of commonly co-morbid and clinically-linked conditions (described in section 20.1.3.1 of Chapter 16b); or
- An MA organization-customized group of multiple chronic conditions (described in section 20.1.3.2 of Chapter 16b).

CMS recognizes that there is value for C–SNPs to use groupings of severe or disabling chronic conditions in identifying their focus and limiting enrollment, and our proposals reflect how the MA organizations that offer C–SNPs must choose a single chronic condition from the definition of severe or disabling chronic condition or choose from a list of permitted multiple chronic conditions found in in the new subparagraphs (A) and (B) under § 422.4(a)(1)(iv).

First, we are proposing, as part of the definition of C–SNP at § 422.2 and in the description of special needs plans at § 422.4(a)(1)(iv), to codify current guidance regarding the ability of MA organizations to offer a C–SNP that focuses on single or multiple chronic conditions. The proposed definition of chronic condition special needs plan (C–SNP) provides that C–SNPs are SNPs that restrict enrollment to MA special needs eligible individuals who have a severe or disabling chronic condition as defined in § 422.2 under this section. In other words, the chronic conditions on which a C–SNP may focus are limited to those conditions listed in the definition of severe or disabling chronic condition. When a C–SNP focuses on one chronic condition, enrollees must have that severe or disabling chronic condition in order to enroll in the C–SNP. In addition to single chronic condition category PBPs, CMS currently permits MA organizations to apply to offer a C–SNP that includes specific combinations of CMS-approved group of commonly co-morbid and clinically linked conditions, as described in section 20.1.3.1 of Chapter 16b of the MMCM. We are proposing to codify how a C–SNP may focus on multiple chronic conditions in two ways. The proposed definition of C–SNP provides that the restricted enrollment to individuals with severe or disabling chronic conditions includes restricting enrollment based on the multiple commonly co-morbid and clinically-liked conditions groupings specified in § 422.4(a)(1)(iv) of this chapter.

Currently, CMS has identified five combinations of commonly co-existing chronic conditions that may be the focus of a C–SNP based on our data analysis and recognized national guidelines. The current set of combinations include:

- Diabetes mellitus and chronic heart failure;
- Chronic heart failure and cardiovascular disorders;
- Diabetes mellitus and cardiovascular disorders;
- Diabetes mellitus, chronic heart failure, and cardiovascular disorders; and
- Stroke and cardiovascular disorders.

As of March 2022, MA organizations offered 178 C–SNPs covering more than one chronic condition. A majority of these plans (151) represent a grouping of just three commonly co-morbid and clinically-linked conditions: cardiovascular disease, congestive heart failure (CHF), and diabetes mellitus. Another 21 plans represented a combination of cardiovascular disease and CHF. C–SNPs have tended to focus on combinations of these three specific conditions since this policy was implemented. Considering the established clinical connection between these conditions and the interest among plans and beneficiaries, we propose to maintain the current list. We are proposing to codify this current list of combinations of chronic conditions that may be used by a C–SNP at § 422.4(a)(1)(iv)(A)(*1*) through (*5*).

A C–SNP may not be structured around multiple commonly co-morbid conditions that are not clinically linked in their treatment because such an arrangement results in a general market product rather than one that is tailored for a particular population. As part of its review, the 2019 clinical advisor panel convened in accordance with section 1859(f)(9)(A) of the Act recommended the continuation of the current Chapter 16b linked conditions plus three additional groups. The panel considered a number of relevant factors, including all statutory criteria required under the Act, when determining the appropriateness of additional pairings, including clinical considerations and the potential of these conditions to be successfully managed by a specialized provider network. The panel recommended the following additional groupings conditions were as follows:

- Anxiety associated with COPD.
- CKD and post-renal organ transplantation.
- Substance Use Disorder (SUD) and Chronic and disabling mental health conditions.

In addition to our proposal to codify the current approved set of commonly co-morbid and clinically-linked conditions, we propose to add the three

recommended pairings as permissible groupings of severe or disabling chronic conditions that may be used by C–SNPs at new § 422.4(a)(1)(iv)(B)(*6*) through (*8*). Under this proposal, a C–SNP may focus on one of the commonly co-morbid and clinically-linked conditions specified in these eight specific combinations of co-morbid condition groupings upon CMS approval. We are also proposing to add a new paragraph (a)(1)(iv)(A) at § 422.4 to clarify that enrollees need only have one of the qualifying conditions for enrollment listed in the approved groupings in proposed paragraph (a)(1)(iv)(B). This is consistent with current CMS operational practices regarding the current set of approved C–SNP groups. We are seeking comment on our proposal to codify the current list of five commonly co-morbid and clinically-linked conditions. We are also seeking comment on the applicability of the proposed set of three new chronic condition pairs based on the chronic condition panel's recommendations. Second, we are also proposing to add at a new paragraph (g) at § 422.52 that SNPs may enroll eligible beneficiaries into a C–SNP consisting of commonly co-morbid and clinically-linked conditions if the beneficiary has only one of the qualifying conditions for enrollment.

Lastly, CMS is not proposing to codify a C–SNP plan application option that is currently available under subregulatory guidance in section 20.1.3.2 of Chapter 16b of the MMCM. In effect, this will remove this approach as an option for C–SNPs beginning 2024. Under the current guidance, we permit MA organizations seeking to sponsor a C–SNP to apply for an MA organization-customized group of multiple chronic conditions. If a C–SNP uses such a customized group of conditions, enrollment in that C–SNP is limited to special needs individuals who have all of the severe or disabling conditions in the group. CMS has reviewed only a few SNP plan application proposals since the initial implementation of the C–SNP program and has not granted any applications either due to the lack of clinical connection between the proposed conditions or because the MA organization failed to meet other conditions of the application process. No C–SNPs of this type have been approved nor will be operational in CY 2023. We are proposing to remove this option from the C–SNP application process beginning in CY 2024. Given the historical lack of interest from MA organizations, beneficiaries, or patient advocacy groups, we believe there will be minimal impact on stakeholders associated with the elimination of this current flexibility. In addition, with the addition of three new groupings and the ability to establish a C–SNP that is based on functional limitations that we are proposing with paragraphs (20) through (21) of the proposed definition of severe or disabling chronic condition, we believe that there is adequate flexibility for MA organizations to develop C–SNPs that meet the needs of the Medicare population.

In conclusion, we are proposing to define C–SNPs at § 422.2 as SNPs that restrict enrollment to MA eligible individuals who have a severe or disabling chronic condition as defined under § 422.2. We are proposing to amend § 422.4(a)(1)(iv) to limit C–SNPs that focus on multiple chronic conditions to the list of CMS-approved group of commonly co-morbid and clinically linked conditions. And we are proposing to amend § 422.52 to clarify that enrollees need only have one of the qualifying conditions for enrollment when a C–SNP focuses on multiple conditions in one of the groupings specified in proposed § 422.4(a)(1)(iv)(B). This will provide greater clarity for MA organizations seeking to establish combination plans and for Medicare beneficiaries exploring potential MA plan options. We are seeking comment on these proposals.

Many of the changes we are proposing in connection with C–SNPs, including the revision of the definition of severe and disabling chronic condition and the new definition of C–SNP, would unify and streamline existing requirements, which should reduce burden and are therefore not expected to have impact. The proposal regarding the definitions of severe or disabling chronic condition and C–SNP and the amendments to §§ 422.4(a)(1)(iv) and 422.52 would be applicable beginning with plan year 2024. Together, these proposals would implement the new list of chronic conditions recommended by the panel of clinical advisors established by section 1859(f)(9)(A) of the Act. Our proposed update to the list would create new chronic condition categories, relabel several existing categories, and include several new sub-conditions ''under a number of chronic conditions. It is unclear how many MA organizations would create new C–SNPs based on the proposed new list of severe or disabling chronic conditions that meet the criteria in section 1859 of the Act. Historically, MA organizations have generally focused plan and benefit efforts around a few specific chronic conditions. As reflected on Table D–A 1, C–SNPs based on just three conditions make up 63 percent of all C–SNPs created since 2007: Cardiovascular Disorders, Chronic Heart Failure, and Diabetes Mellitus.[148] Given this historical pattern, we expect that MA organizations may be slow or hesitant to create new C–SNP plan type options around the new set of chronic conditions.

We anticipate that changes from current plan and enrollment practices would most likely be seen in connection with chronic condition categories like ESRD, where the proposal would somewhat revise enrollment qualifications. Based on the proposal to use the condition category ''Chronic kidney disease (CKD)'' and to include ESRD as part of that condition category, we expect that current ESRD C–SNPs will be permitted to enroll, in addition to those with ESRD, beneficiaries with CKD Stages 1–4 once this proposal is finalized. As of July 2022, CMS contracts with 17 C–SNPs for ESRD. CMS estimates that just under 23 percent of Medicare beneficiaries qualify for one of the stages of CKD; however, this figure includes beneficiaries who may already qualify for an ESRD C–SNP in their area.[149] However, we have no clear evidence to suggest how this will impact enrollment for current ESRD plans potentially impacted by this proposal or new C–SNPs that would be created because of it.

Because MA organizations would be able to choose to create and submit a C–SNP under one of the new chronic condition categories starting in CY 2024 (with the exception CKD as proposed in section IV.A.1. of this proposed rule), we do not see this as a new burden. The burden associated with the MA application process is covered under PRA CMS–10237/OMB 0938–0935, while the burden associated with complying with the SNP MOC process is covered under PRA CMS–10565/OMB 0938–1296. The proposals here, if finalized, would add no additional burden for MA organizations sponsoring a C–SNP now or in the future. The proposed policy would allow MA organizations to select new C–SNP plan

[148] Table D–A 1 was created using data from CMS' SNP Comprehensive Report, found here: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.* Data was collected by sampling reports from May 2007 through January 2022. Data from reports was then coded and analyzed to create a distribution of C–SNP plan types.

[149] This 2018 estimate is based on the CMS Office of Enterprise Data and Analytics analysis of chronic conditions identified using ICD–10 codes. Additional information can be found here: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.*

type options, but it would not compel them to do so. However, we would monitor all C–SNP type applications for CY 2025 and future years to inform future implementation strategies and impact on the program.

TABLE D-A 1. DISTRIBUTION OF C-SNPS BY CHRONIC CONDITION 2007 – 2022

Chronic Condition Category	Frequency	Percent
Cardiovascular Disorders, Chronic Heart Failure, and Diabetes	730	28
Diabetes	539	21
Chronic lung disorders	265	10
Multiple conditions, 4+ (2007-2010)	192	7
Chronic Heart Failure and Diabetes	164	6
Cardiovascular Disorders and Chronic Heart Failure	152	6
ESRD	144	6
Unknown and Plans < 11 members	132	5
Dementia	52	2
HIV/AIDS	52	2
Chronic and disabling mental health conditions	43	2
Chronic lung disorders; Diabetes	27	1
Diabetes and Hypertension	20	1
Chronic Heart Failure	19	1
Pulmonary Disease and Diabetes	18	1
Hypercholesterolemia	12	< 1
Dyslipidemia	11	< 1
Cardiovascular Disorders	9	< 1
Obesity	3	< 1
Chronic lung disorders; ESRD; Diabetes	3	< 1
Cardiovascular Disorders and Diabetes	2	< 1
CKD/Chronic Renal Failure and ESRD	2	< 1
Hypertension	2	< 1
Diabetes, Cardiovascular Disease, and Stroke	2	< 1
Hypertension, Diabetes, and Dyslipidemia	1	< 1
congestive heart failure; ischemic stroke; coronary artery disease	1	< 1
Congestive heart failure and Chronic obstructive pulmonary disease	1	< 1
Chronic Kidney disease; ESRD; post-transplant; Kidney Transplant; Post-Transplant	1	< 1
Chronic alcohol use disorder and other substance use disorders	1	< 1

B. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§ 422.2)

Institutional Special Needs Plans (I–SNPs) are MA special needs plans (SNPs) that restrict enrollment to MA-eligible individuals who are institutionalized or institutionalized-equivalent as those terms are defined in § 422.2. Institutionalized is defined, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), as 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: skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare); nursing facility (NF) as defined in section 1919 of the Act (Medicaid); intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act; psychiatric hospital or unit as defined in section 1861(f) of the Act; rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act; long-term care hospital as defined in section 1886(d)(1)(B) of the Act; hospital which has an agreement under section 1883 of the Act (a swing-bed hospital); and last, subject to CMS approval, a facility that is not listed as part of the definition of ''Institutionalized'' at § 422.2 but meets both of the following: furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and whose residents have similar needs and healthcare status as residents of one or more facilities listed in the definition of ''Institutionalized'' at § 422.2. We define, at § 422.2, the term ''institutionalized-equivalent,'' for the purpose of identifying a special needs individual, as an MA eligible individual who is living in the community, but requires an institutional level of care; in addition, the definition of the term ''institutionalized equivalent'' includes specific limitations on how an assessment is made that an individual meets the definition.

Per the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), I–SNPs, along with C–SNPs and D–SNPs, are MA plans that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859(b)(6)(B) and (f)(1) of

the Act, I–SNPs restrict enrollment to MA eligible individuals who meet the definitions of ''institutionalized'' or ''institutionalized-equivalent'' in § 422.2, which are based on section 1859(b)(6)(B)(i) and (f)(2)(A) of the Act. As of February 2022, there are 87 I–SNP MA contracts with 186 plans serving 96,792 enrollees.[150] CMS currently permits MA organizations to submit SNP applications that are restricted to institutionalized individuals only or institutionalized-equivalent individuals only, as defined in § 422.2 respectively, or to submit an application for a combination SNP that covers beneficiaries who qualify for either institutionalized or institutionalized-equivalent status, but are enrolled under the same plan.

We propose to add four definitions at § 422.2: a definition of I–SNPs and three additional definitions for each of the current I–SNP types that correspond to CMS' current MA application process. In addition, we propose to codify, as part of the definitions for I–SNPs that enroll special needs individuals who are institutionalized, current policies that address the need for the I–SNP to contract with the institutions where such special needs individuals reside. We believe that adding these four definitions will help clarify the specific standards that are applicable to I–SNPs, as distinguished from other MA plans and from other MA SNPs. This proposal includes tying the definitions of institutionalized and institutionalized-equivalent in § 422.2 and the list of eligible institutions set forth in that definition, to our proposed definition of I–SNP. This approach is consistent with how CMS has adopted regulatory definitions for D–SNPs, FIDE SNPs, and HIDE SNPs in § 422.2. The proposed definitions clarify that MA organizations may offer SNPs that are: exclusive to beneficiaries meeting the definition of institutionalized under § 422.2; are exclusive to beneficiaries meeting the definition of institutionalized-equivalent under § 422.2; or are exclusive to beneficiaries who meet either of those definitions. Our proposed language linking I–SNP enrollment to the definitions noted here matches current subregulatory guidance and practice used by CMS during the MA application process for I–SNPs.

Lastly, we are proposing to amend § 422.101(f)(2) to add a requirement that the models of care for I–SNPs ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in § 422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized. This proposed new paragraph (f)(2)(vi) would codify longstanding subregulatory guidance in section 20.3 of Chapter 16b of the MMCM that is designed to provide I–SNPs enrollees protections regarding access to care coordination and communication between providers and I–SNP staff. Under our proposal, I–SNP clinical and care coordination staff may be employed by the MA organization offering the I–SNP or under contract with the I–SNP to furnish healthcare, clinical or care coordination services. CMS has received feedback in the past that institutional providers sometimes fail to share relevant information regarding an I–SNP enrollee's health status or need for care or services with the I–SNP staff. We intend that codifying this requirement for I–SNP MOCs to ensure that the contracts between the I–SNP and these institutions where I–SNP enrollees reside include provisions allowing access for I–SNP staff will protect beneficiaries. Our proposal would leave the details of how access to I–SNP enrollees would be assured for I–SNP staff but we intend the term ''access'' to be interpreted broadly to encompass information sharing, admission to physical facilities to see enrollees, and other issues. We are seeking comment on whether the regulation text needs to more specifically address information sharing or other related issues. We believe that codifying this policy would improve transparency for stakeholders, improve care coordination and ensure the continuity of care for vulnerable beneficiaries. In the years since it was issued in 2016, we have used the I–SNP guidance from section 20.3 of Chapter 16b to administer policies central to plan compliance and application review. In that time, I–SNP enrollment has grown from 54,643 enrollees under 37 contracts and 79 plans to 96,792 enrollees being served by 87 I–SNP MA contracts with 186 plans.[151] As of 2021, MedPAC shows that 72 percent of Medicare beneficiaries have access to at least one I–SNP plan, up from 52 percent in 2017.[152] As MedPAC noted in its March 2013 report, I–SNPs perform better than other SNPs and other MA plans on the majority of available quality measures for SNPs. MedPAC also noted in the same report that I–SNPs had much lower than expected hospital readmission rates and scored just as well as D–SNPs and C–SNPs on other measures.[153] From an administrative standpoint, CMS has found I–SNPs to be comparable to other SNPs when it comes to meeting compliance standards.

Section 1859(f) of the Act includes additional requirements for all types of specialized MA plans for special needs individuals and requirements specific to I–SNPs. Per the current definition of specialized MA plan for special needs individuals in § 422.2, MA SNPs must all cover Part D benefits under part 423 for their enrollees. In addition, the definition of MA SNPs provides that these MA plans have been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population. The proposed definition of the term ''institutional special needs plan (I–SNPs)'' uses the term ''specialized MA plan for special needs individuals'' and therefore incorporates the requirements and limitations on SNPs that are included in that definition in § 422.2. Accordingly, we are proposing to define I–SNPs as SNPs that restrict enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent in this section. We are also proposing to include in our definition of I–SNP that there are the following types: I–SNP Institutionalized, I–SNP Equivalent, and I–SNP Hybrid. We believe this definition is consistent with our current guidance and operational practices involving I–SNPs and Medicare beneficiaries enrolled in those plans such that this proposal represents a continuation of I–SNP policies.

We are also proposing to define three I–SNP types that are currently used by

[150] See ''SNP Comprehensive Report 2022 02,'' found here: *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldataspecial-needs/snp-comprehensive-report-2022-02.*

[151] See ''SNP Comprehensive Report 2016 01,'' found here: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data-Items/SNP-Comprehensive-Report-2016-01;* and ''SNP Comprehensive Report 2022 02,'' found here: *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldataspecial-needs/snp-comprehensive-report-2022-02.*

[152] See Chapter 12: The Medicare Advantage program: Status report (March 2021), found here: *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch12_sec.pdf.*

[153] The full report, ''Chapter 14: Medicare Advantage special needs plans'' (March 2013), can be found here: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-14-medicare-advantage-special-needs-plans-march-2013-report-.pdf.*

CMS to operationalize MA applications and Medicare beneficiary enrollment into I–SNPs. The proposed definitions address both enrollment limitations used by these different types of I–SNPs and certain performance and contracting requirements that are specific to each type. Each new definition would be added to § 422.2.

Our first proposed definition is an I–SNP type that enrolls only Medicare beneficiaries who meet the definition of institutionalized in § 422.2. We proposing to call these I–SNPs ''Facility-based Institutional Special Needs plans'' or FI–SNPs. In addition to the enrollment criteria noted in this paragraph, the proposed definition provides that FI–SNPs must own or have a contractual arrangement with at least one institution specified in the definition of institutionalized in § 422.2 for each county within the plan's service area and with each institutionalized facility serving enrollees in their plan. The latter two requirements represent codifications of longstanding subregulatory guidance in section 20.3 of Chapter 16b of the MMCM.

We are proposing a definition for a second I–SNP type called ''Institutional-equivalent Special Needs Plan'' or IE–SNP. IE–SNPs are an I–SNP type that restricts enrollment to MA eligible individuals who meet the definition of institutionalized-equivalent in § 422.2. Those special needs individuals are living in the community but require an institutional level of care, which is determined using assessment tools that meet requirement specified in the definition of the term institutionalized-equivalent. The determination that a Medicare beneficiary requires an institutional level of care (LOC) must be made using a State assessment tool from the State in which the individual resides and the LOC assessment must be conducted by an impartial party with the requisite knowledge and experience to accurately identify whether the beneficiary meets the institutional LOC criteria. CMS has interpreted the standard that the assessment be done by an impartial entity as requiring that the entity be other than the I–SNP and that the I–SNP cannot own or control the entity. CMS currently uses the IE–SNP designation for operational purposes during the MA application review and approval process.

We are proposing a definition for a third I–SNP type called ''Hybrid Institutional Special Needs Plan.'' HI–SNPs are I–SNP type that restricts enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent. For enrollees that meet the definition of institutionalized, the HI–SNP must own or contract with at least one institution, as determined under the definition of institutionalized in this section, for each county within the plan's county-based service area; and must own or have a contractual arrangement with each institutionalized facility serving enrollees. In other words, we are proposing that HI–SNPs meet the standards specified in the definitions of FI–SNPs and HE–SNPs since these hybrids serve both type of special needs individuals. CMS currently uses the HI–SNP designation for operational purposes during the MA application review process.

CMS's current guidance for I–SNPs in section 20.3.4 of Chapter 16b of the MMCM addresses a number of requirements that the contract between the I–SNP and the LTC facility must include in order for an I–SNP to meet CMS compliance in addition to the requirement, proposed to be added to § 422.101(f)(2)(vi), that the I–SNP model of care ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in § 422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized. Some of that guidance addressing an I–SNP's relationship with long-term care institutions is proposed to be included in the definitions for specific types of I–SNPs. We are not proposing to codify the remainder of the requirements listed in section 20.3.4 of Chapter 16b because they would duplicate requirements in other current MA regulations under part 422. Specifically, we believe the following standards described in section 20.3 are addressed or required by current regulations:

- Section 20.3.4 states that facilities in a chain organization must be contracted to adhere to the I–SNP MOC. Currently, requirements for compliance with and implementation of the I–SNP's required model of care (MOC) by the LTC facilities and other providers that contract with the I–SNP to furnish services to the I–SNP's enrollees are addressed by §§ 422.101(f)(2), 422.202 and 422.504. Currently, all SNPs are required under § 422.4(a)(1)(iv) to submit their model of care (MOC) to CMS for National Commission on Quality Assurance (NCQA) evaluation and approval. All SNPs (including I–SNPs) are required by § 422.101(f)(2) to have appropriate employed, contracted, or non-contracted staff trained on the SNP plan MOC to coordinate and/or deliver all services and benefits; and in addition, SNPs must develop and implement model of care requirements to coordinate the delivery of care to their enrollees across healthcare settings, providers, and services to assure continuity of care. Per § 422.202, MA organizations are required to provide information about the rules of participation in the organization's network of providers and to have a mechanism for consulting with and communicating practice guidelines and utilization management guidelines to contracted providers. Finally, § 422.504(i) provides that MA organizations must include certain provisions and beneficiary protections in their contracts with first tier, downstream and related entities (which includes contracted providers), including compliance with Medicare laws and the MA organization's contractual obligations with CMS. Thus, we believe codifying this aspect of the existing guidance would be duplicative. We solicit comment from providers whether an additional regulation specific to this issue is necessary to further clarify the obligations of I–SNPs.
- Section 20.3.3 provides that an I–SNP must document that it is prepared to implement the approved MOC when an enrollee changes residence or LTC facility that furnishes services to the I–SNP's enrollees. If an I–SNP enrollee changes applicable facility status, the I–SNP must document that it is prepared to implement the approved MOC at the enrollee's new residence or in another I–SNP contracted LTC setting that provides an institutional level of care. Again, we believe a regulation that is specific to this issue would be duplicative of existing regulations. All SNPs, including I–SNPs, are required under § 422.101(f)(2)(ii) to have contracted staff trained on the MOC. In addition, per § 422.101(f)(1), SNPs must develop and implement individualized plans of care for enrollees and use interdisciplinary teams to manage and furnish care; we believe that in order to meet those obligations, an I–SNP would necessarily have to involve and coordinate services with the long-term care facility (LTCF) where an enrollee receives services.
- Section 20.3.4 of Chapter 16b also addresses how:

++ The I–SNP must provide protocols to all LTCFs for serving the I–SNP's enrollees in accordance with the approved I–SNP MOC, and the contract with each LTCF must reference these protocols.

++ The I–SNP must clearly specify in its contract with the LTCF provider the services to be provided to I–SNP

enrollees by the LTCF and its staff, in accordance with the protocols and payment for the services provided by each LTCF. The I–SNP must include in its contract with the LTCF provider a training plan to ensure that LTC facility staff understands their responsibilities in accordance with the approved I–SNP MOC, protocols, and contract. If the training plan is a separate document, then the contract should reference it.

Like the other issues previously discussed, these actions are required in order for an I–SNP to meet their obligations to coordinate and implement the approved MOCs and to maintain effective oversight over first tier, downstream and related entities involved in the furnishing of covered benefits to enrollees under §§ 422.101(f) and 422.504. We believe additional regulations that are specific to how §§ 422.101(f) and 422.504 work together in this context would be unnecessary and duplicative.

- Section 20.3.4 provides that I–SNPs must develop procedures for LTCFs to maintain a list of credentialed I–SNP clinical staff in accordance with the LTC facility's responsibilities under Medicare conditions of participation. Per § 422.204(b)(2), MAOs must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements in meeting the initial credentialing and recredentialing requirements. In addition, per § 422.204(b)(3), the I–SNP can only contract with a LTCF (which is a provider of services as that term is defined in section 1861(u) of the Act) for furnishing Part A and B benefits when the facility has a Medicare participation agreement, which would include the obligations to comply with conditions of participation in 42 CFR part 483. We believe that an additional regulation that specifies that I–SNPs must include in their contracts with LTCFs that the LCTFs comply with their Medicare conditions of participation would be unnecessarily duplicative.
- Section 20.3.4 of Chapter 16b provides that I–SNPs must ensure that the contract between the I–SNP and the LTCF where enrollees of the I–SNP reside must specify the start and end date of the contract; the guidance also states that the contract should include the full CMS contract cycle, which begins on January 1 and ends on December 31. The I–SNP may also contract with additional LTC facilities throughout the CMS contract cycle. To the extent that this guidance goes beyond requirements in § 422.504(i), we do not believe that it is necessary to adopt a regulation to require these specific contract terms for I–SNPs and their contracted LTCFs. The proposed definitions for the I–SNPs that serve beneficiaries that are institutionalized would require those MA plans to have contracts with the LTCFs where enrollees reside and with LTCFs in the service area; in order to meet these requirements during the full term of the I–SNP's contract with CMS, those contracts would necessarily have to cover the full January through December time frame. We do not believe that a more detailed regulation governing the terms of contracts between I–SNPs and LTCFs on this point is necessary.
- Finally, section 20.3.4 of Chapter 16b provides that the contract between the I–SNP and the LTCF include a termination clause that clearly states any grounds for early termination of the contract and a clear plan for transitioning the enrollees to another facility where the I–SNP can furnish covered benefits should the I–SNP's contract with the LTC facility terminate. In addition, a transition plan would only be necessary if the beneficiary elects to continue enrollment with the I–SNP rather than elect enrollment in a different MA plan or Original Medicare. Further, we note that a beneficiary who remains in the terminated facility or who transfers to another non-contracted facility would lose eligibility for enrollment in their current I–SNP. Section 422.504(i) requires MA organizations to include in their contracts with first tier, downstream and related entities provisions that address termination and scope of the activities to be performed by the contracted entity; this regulation applies to contracts between the MA plan and providers. In addition, SNPs are required to implement the MOC under § 422.101(f) with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees and to have individualized plans of care for each enrollee; ensuring the continued delivery of services during a period of transition would necessarily have to be addressed in implementation of the MOC and plans of care. Therefore, we are not proposing an additional regulation to codify this aspect of our current guidance.

The changes that we are proposing carry no burden. We are proposing definitions of I–SNP and I–SNP types under § 422.2 to clarify existing policies that are specific to I–SNPs and not general policies impacting D–SNPs or C–SNPs. This proposal is also a codification of several specific longstanding subregulatory guidance in Chapter 16b of the MMCM. We believe there is no burden associated with either pieces of our proposal, as the creation of a definition will not engender operational or policy changes impacting MA organizations sponsoring I–SNPs nor impact enrollees; likewise, we do not expect any burden associated with the continuation of existing guidance that was incorporated and implemented with the release of the 2016 update of Chapter 16b of the MMCM.

We are seeking comment on the proposed codification of chapter 16b subregulatory guidance and the proposed new definition of I–SNP. In particular, we are seeking feedback on I–SNP operationalization of the current subregulatory guidance. We also seek feedback from commenters who have other suggestions for improving the care furnished to the special needs individuals enrolled in I–SNPs, many of whom are dually eligible for Medicare and Medicaid, based on parallels or lessons learned from other State or Federal programs administering services to long-term care residents or beneficiaries requiring a nursing home level of care.

C. Definition of Network-Based Plan (§§ 422.2 and 422.114)

This proposed revision would move the current definition of a network-based plan from § 422.114(a)(3)(ii) to the definitions section in § 422.2. This proposed change has no implications for other provisions in part 422 in which the definition or description of network plans play a role, for example, the network adequacy provisions at § 422.116 and the plan contract crosswalk provisions at § 422.530. Currently, § 422.116(a)(1)(i) references the current definition of network-based plan at § 422.114(a)(3)(ii) in its specification of network adequacy requirements for the various plan types. We propose to make, however, a conforming change to § 422.116(a)(1)(i) consistent with our proposal to move the definition of network-based plan; this conforming change is to reference § 422.2. The regulation at § 422.530(a)(5) specifically addresses the types of plans to which it applies and when CMS considers a crosswalk to be to a plan of a different type, so we do not believe any amendment to § 422.530 is necessary in connection with moving the definition of network based plan to § 422.2.

Private-fee-for-service (PFFS) plans were established by the Balanced Budget Act of 1997 and were originally not required to have networks. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) revised

the PFFS requirements to require that beginning contract year 2011 any PFFS plan operating in the same service area as two or more network-based plans also have a network. For purposes of this requirement, section 1852(d)(5)(C) of the Act and § 422.114(a)(3)(ii) define network-based plans as a coordinated care plan (as described in section 1851(a)(2)(A) of the Act and § 422.4(a)(1)(ii)), a network-based MSA plan, and a section 1876 reasonable cost plan. The statutory and regulatory definitions both specifically exclude an MA regional plan that meets access requirements substantially through means other than written contracts, per § 422.112(a)(1)(ii).

When codifying this requirement in the final rule that appeared in the **Federal Register** September 18, 2008 titled ''Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs'', (73 FR 54226), we included the definition of network-based plan in the section of the regulations for PFFS plans, as the definition was integral to the new requirement for PFFS plans. (73 FR 54230, 54249) A network-based plan, however, has meaning in contexts other than in addressing these specific requirements for MA PFFS plans and, in order to ensure that the definition is more readily accessible for those seeking requirements related to network-based plans, we are proposing to move it to the definitions section at § 422.2. The PFFS section at § 422.114(a)(3)(ii) would continue to include language specifying the network requirement, but the proposed conforming change to this section would refer to the definitions in § 422.2 instead of including the definition in § 422.114(a)(3)(ii).

D. Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)

Section 231 of the Medicare Modernization Act of 2003 (MMA) amended section 1851(a)(2)(A)(ii) of the Act to establish specialized MA plans for special needs individuals. Special needs plans (SNPs), defined at section 1859(b)(6)(A) of the Act, are plans with limited enrollment, specifically designed to provide targeted care to institutionalized individuals, dual eligible individuals, or individuals with severe or disabling chronic conditions, collectively known as a ''special needs individual'' as defined at section 1859(b)(6)(B) of the Act. Only those individuals who qualify as special needs may enroll, and remain enrolled, in a SNP. In the January 2005 MA final rule, we established regulations at § 422.52 that provided that to be eligible to enroll in a SNP, an individual must meet the definition of a special needs individual, meet the eligibility requirements for that specific SNP, and be eligible to elect an MA plan. Sections 1859(b)(6)(B) and 1894(c)(4) of the Act, and CMS's implementing regulation at § 422.52(d), allow individuals who lose special needs status, if, for example, they were to no longer have the level of Medicaid eligibility or other qualifying condition necessary to be eligible for the plan, to have a period of deemed continued eligibility if they are reasonably expected to regain special needs status within, at most, the succeeding 6-month period. The period of deemed eligibility must be at least 30 days but may not be longer than 6 months. In implementing regulations, we also established loss of special needs status (and of deemed continued eligibility if applicable) as a basis for required disenrollment at § 422.74(b)(2)(iv).

The January 2005 MA final rule served as the basis for our current sub-regulatory guidance in Chapter 2 of the Medicare Managed Care Manual, Section 50.2.5, which specifically provides that plans send certain notices prior to and following the effective date of involuntary disenrollment based on loss of special needs status. These policies are intended to ensure that beneficiaries are given adequate notice prior to being disenrolled from a SNP and provided an opportunity to prove that they are eligible to remain enrolled in the plan, if applicable. Providing these members at least 30 days advance notice of disenrollment, along with information about deemed continued eligibility and eligibility for an SEP to elect other coverage, gives beneficiaries ample time to prove they are still eligible for their SNP or to evaluate other coverage options.

To provide stability and assurance about the requirements for MA organizations in these situations as well as transparency to stakeholders, we are proposing to codify current policy for MA plan notices prior to a member's disenrollment for loss of special needs status, as well as a final disenrollment notice. We intend that stakeholders will be able to rely on these regulations, and that these regulations would only be changed through a subsequent rulemaking, establishing the procedures that an MA organization must follow in the event that a SNP enrollee loses special needs status and is disenrolled from the SNP on that basis. Specifically, we are proposing to revise § 422.74(d) by redesignating paragraph (d)(8) as paragraph (9) and adding new paragraph (8), to state that the plan would be required to provide the enrollee a minimum of 30 days advance notice of disenrollment, regardless of the date of the loss of special needs status. As proposed in new paragraphs (8)(i) and (ii), an advance notice would be provided to the enrollee within 10 calendar days of learning of the loss of special needs status, affording the enrollee an opportunity to prove that he or she is still eligible to remain in the plan. The advance notice would also include the disenrollment effective date, a description of SEP eligibility, as described in § 422.62(b)(11), and, if applicable, information regarding the period of deemed continued eligibility, the duration of the period of deemed continued eligibility, and the consequences of not regaining special needs status within the period of deemed continued eligibility. Additionally, as proposed in new paragraph (8)(iii), the plan would be required to provide the enrollee a final notice of involuntary disenrollment within 3 business days following the disenrollment effective date, which is either the last day of the period of deemed continued eligibility, if applicable or a minimum of 30 days after providing the advance notice of disenrollment, and must be sent before submission of the disenrollment to CMS. Lastly, we propose in new paragraph (8)(iv), that the final involuntary disenrollment notice must include an explanation of the individual's right to file a grievance under the MA organization's grievance procedures, which are required by § 422.564.

We are codifying longstanding guidance with these changes. Based on infrequent questions or complaints from MA organizations and enrollees on these notices, we believe that these notice requirements have been previously implemented and are currently being followed by plans. We do not believe the proposed changes to the regulatory text will adversely impact MA organizations or individuals enrolled in MA special needs plans who lose special needs status, other than the appropriate disenrollment from the plan due to the individual's loss of eligibility for the plan. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

E. Involuntary Disenrollment for Individuals Enrolled in a MA Medical Savings Account (MSA) Plan (§ 422.74)

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1851(a)(2) of the Act

establishing private health plan options available through Part C of the Medicare program known originally as ''Medicare + Choice'' and later as ''Medicare Advantage (MA).'' Under this program, eligible individuals may elect to receive Medicare benefits through enrollment in one of an array of private health plan choices beyond the original Medicare program. As enacted, section 1851(a)(2)(B) of the Act established the authority for an MA organization to offer a MA medical savings account (MSA) option which is, a combination of a high-deductible MA plan, as defined in section 1859(b)(3) of the Act, with a contribution into a Medical Savings Account (MSA).

In the interim final rule titled Medicare Program; Establishment of the Medicare+Choice Program,'' published in the **Federal Register** June 26, 1998 (63 FR 34968), we established the conditions for MA organizations to enroll individuals in a MA MSA plan. The restrictions on enrollment in MA MSA plans were set forth under section 1851(b)(2) and (b)(3) of the Act and in implementing regulations at § 422.56. Specifically, consistent with section 1851(b)(2) of the Act, § 422.56(b) provides that an individual who is enrolled in a Federal Employee Health Benefits Program (FEHB) plan, or is eligible for health care benefits through the Veterans Administration (VA) or the Department of Defense (DoD), may not enroll in a MA MSA plan. In addition, § 422.56(c) incorporates the statutory prohibition under section 1851(b)(3) of the Act on enrollment in MA MSA plans by individuals who are eligible for Medicare cost-sharing under Medicaid State plans. Additional restrictions were set forth under section 1852(a)(3)(B) of the Act and in implementing regulations at § 422.56(d) based on supplemental benefits under an MA MSA plan.

The January 2005 MA final rule implemented section 233 of the Medicare Modernization Act, which lifted the time and enrollment limits on MSA plans imposed by the BBA of 1997. However, section 233 of the MMA did not alter the prohibitions in sections 1851(b)(2) and (b)(3) of the Act on enrollment into an MA MSA plan for individuals covered under other health programs, and likewise the January 2005 MA final rule did not alter the implementing regulations regarding these policies at § 422.56.

The current regulations do not specify whether the eligibility criteria described in § 422.56, which preclude an individual with certain health care coverage from electing an MA MSA plan, are applicable to individuals who gain or become eligible for other coverage *while enrolled in* an MSA plan. In other words, the current regulations do not specify that an individual who ceases to satisfy the eligibility criteria described in § 422.56 while already enrolled in an MA MSA plan must be involuntarily disenrolled from the MSA, regardless of the time of year. CMS has historically understood the eligibility criteria for an individual to be enrolled in an MSA plan in § 422.56, coupled with the statutory prohibitions on enrolling in an MA MSA by individuals with Medicaid or coverage under other health benefits, to mean that an enrollee in an MSA plan is not able to remain a member of the MSA plan and must be disenrolled by the plan when the individual ceases to meet the statutory and regulatory criteria for eligibility. We also note that this policy is consistent with our general approach in section 50.2, Chapter 2 of the Medicare Managed Care Manual, in which an enrollee becomes ineligible due to a status change, such as the loss of entitlement to Medicare Part A or Part B or the inability to regain special needs status during the period of deemed continued eligibility and outlined in § 422.74.

To address more clearly the consequences of the general loss of eligibility in an MSA plan, we are proposing to amend § 422.74 to add new paragraph (b)(2)(vi) to include the requirement that an MA MSA enrollee must be disenrolled, prospectively, due to the loss of eligibility. If an MA MSA enrollee does not provide assurances that he or she will reside in the United States for at least 183 days during the year the election is effective, is eligible for or begins receiving health benefits through Medicaid, FEHBP, DoD, or the VA or obtains other health coverage that covers all or part of the annual Medicare MSA deductible, that enrollee must be involuntarily disenrolled by the MSA plan effective the first day of the calendar month after the month in which notice by the MA organization is issued that the individual no longer meets the MA MSA's eligibility criteria, as proposed in § 422.74(d)(10). We are also proposing to revise § 422.74(c) to require MA MSA plans to provide a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual before the disenrollment transaction is submitted to CMS.

Should an individual's coverage under an MA MSA plan end before the end of a calendar year, CMS recovers from the plan the amount of the lump-sum deposit attributable to the remaining months of that year. This requirement is codified at § 422.314(c). In addition, the disenrolled beneficiary will owe a prorated portion of the current year's deposit amount back to the MA MSA plan. Plans will be able to reconcile and identify MSA deposit amounts for the Current Payment Month (CPM) at the beneficiary-level from the monthly generated MSA Deposit-Recovery Data file. We are proposing at § 422.74(e)(1) that involuntarily disenrolled individuals will be defaulted to enrollment in Original Medicare, which will now pay claims incurred by the former MSA enrollees. Conversely, the former MSA enrollee also has the option to elect to join another MA plan during a valid enrollment period.

F. Codification of Special Needs Plan Model of Care Scoring and Approval Policy (§ 422.101)

Congress first authorized special needs plans (SNPs) to exclusively or disproportionately serve individuals with special needs through passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter referred to as the MMA) (Pub. L. 108–173). The law authorized CMS to contract with Medicare Advantage (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, and institutionalized equivalent individuals who reside in the community but need an institutional level of care when certain conditions are met; (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 2022, 492 SNP contracts with 1,198 SNP plans had at least 11 members. These figures included 307 Dual Eligible SNP contracts (D–SNPs) with 729 D–SNP plans with at least 11 members, 87 Institutional SNP contracts (I–SNPs) with 186 I–SNP plans with at least 11 members, and 98 Chronic or Disabling Condition SNP contracts (C–SNPs) with 283 C–SNP plans with at least 11 members. SNPs as of June 2022 serve 4,897,054 MA enrollees, with D–SNPs enrolling 4,385,315, C–SNPs with

409,931, and I–SNPs with 100,808 members.

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, which are in section 1859(f)(5)(A) of the Act. As a result, all SNPs are required to implement care management requirements which have two explicit components: an evidence-based model of care (MOC) and a series of care management services. For more discussion of the history of SNPs, please see Chapter 16b of the Medicare Managed Care Manual (MMCM).

This proposed rule would codify certain subregulatory guidance from Chapters 5 and 16b of the MMCM about current SNP MOC scoring protocols; annual C–SNP MOC submissions as required by the BBA of 2018; and processes for amending SNP MOCs after National Committee for Quality Assurance (NCQA) approval.

1. Codification of Model of Care (MOC) Scoring Requirements for Special Needs Plans (SNPs) (§ 422.101)

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. In the final rule titled Medicare and Medicaid Programs; Contract Year 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, which appeared in the **Federal Register** on January 12, 2021 (hereinafter referred to as the January 2021 final rule), we adopted several regulatory amendments to implement requirements for the SNP MOC that were enacted as part of the BBA of 2018 and our extension of some C–SNP-specific standards to all SNP MOCs.

All SNPs must submit their MOCs to CMS for NCQA evaluation. An MA organization sponsoring multiple SNPs must develop a separate MOC to meet the needs of the targeted population for each SNP type it offers. MA organizations that wish to offer a SNP must submit an application (under part 422, subpart K) 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 MOC to be evaluated by the 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 with CMS to offer other MA plans. Most recently, in the January 2021 final rule, CMS revised and amended § 422.101(f) to improve plan implementation of enrollee care management practices and to strengthen the review process by establishing a minimum benchmark score of 50 percent for each element of a plan's MOC (§ 422.101(f)(3)(iii)).

Since the beginning of the MOC approval process, CMS has developed and issued guidance on the MOC to improve plan performance and beneficiary care. CMS provided guidance and instructions in the CY 2010 Final Call Letter issued March 30, 2009, in a section titled, ''Model of Care Reporting for New Applicants and Existing SNPs,'' in order to more clearly establish and clarify delivery of care standards for SNPs.[154] In May, 2008, 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 people with frailty or disability, and those near the end of life based on appropriate protocols. (73 FR 28555, 28559) Section 164 of the MIPPA subsequently added care management requirements for all SNPs in an amendment to section 1859(f)(5) of the Act, outlining new requirements for an evidence-based model of care 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 (HRA) and annual reassessments; (3) an individualized plan of care containing goals and measurable outcomes; and (4) an interdisciplinary team to manage care. The MIPPA amendments to section 1859(f)(5) of the Act laid a statutory foundation for much of our regulatory standards for the model of care. In the September 2008 interim final rule with comment (73 FR 54226, 54228) and the January 2009 final rule (74 FR 1493, 1498), we finalized standards for the required model of care at § 422.101(f).

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. As we noted in the May 2008 proposed rule, CMS deliberately structured its guidance toward the conceptual framework of a MOC without being prescriptive about the specific staff structure, provider network, clinical protocols, performance improvement, and communication systems. We expected SNPs to develop a MOC structure that allowed plans to develop care plans that addressed differing needs among members of the plan. For example, a C–SNP targeting diabetes mellitus may enroll a member with diabetic complications who is near the end of life and might require assisted living or institutional services for which the SNP would develop different goals, expanded specialty services and facilities in their provider network, different performance measures, and additional protocols that would inappropriate for enrollees in the C–SNP who have less severe health complications.

In addition to the requirements in § 422.107(f) for the MOC, CMS has issued guidance over the years, for both NCQA's use in reviewing and approving MOCs and SNPs' use in developing and implementing their MOCs. We believe that, in practice, MOCs are consistent with the existing guidance. The MOC is organized to promote clarity and enhance the focus on care coordination, care transition, care needs and activities. It is a vital quality improvement tool and integral component for ensuring that the unique needs of each enrollee are identified by the SNP and addressed through the plan's care management practices. The NCQA review and approval process is based on scoring each of the clinical and non-clinical elements of the MOC. Each element 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 is in Chapter 5 of the MMCM. CMS also includes the list of elements as part of attachment A (or the MOC Matrix) of the ''Initial and Renewal Model of Care Submissions and Off-cycle Submission of Model of Care Changes'' PRA package (CMS–

[154] The full 2010 Call Letter can be found here: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2010finalcallletter_03.30.09_59.pdf.*

10565).[155] This MOC Matrix is released for public comment prior to the expiration of the PRA package. We are proposing here to codify the SNP MOC scoring protocols by amending § 422.101(f)(3)(iii) to include the current subregulatory scoring protocols. This proposal, and these scoring protocols, align with the minimum benchmark for each element of the SNP MOC of a plan that is currently reflected at § 422.101(f)(3)(iii), as added by the January 2021 final rule. Our adoption of these scoring standards is authorized by section 1859(f)(7) of the Act for NCQA review and approval to be based on standards established by the Secretary and our authority in section 1856(b) of the Act to establish standards to carry out the MA program.

First, we are proposing to amend § 422.101(f)(3)(iii) to add the minimum overall score requirement for approval of a SNP's MOC, using the term aggregate minimum benchmark; we are proposing to use the same minimum standard for the aggregate minimum benchmark as is currently used by NCQA in reviewing and approving MOCs. Currently, SNP MOCs are approved for 1, 2, or 3-year periods. Each element of the SNP's submitted MOC is reviewed and scored. As provided in § 422.101(f)(3)(iii), the minimum benchmark for each element is 50 percent. The MOC is scored by NCQA based on the review of four elements: Description of the SNP Population; Care Coordination; SNP Provider Network; and MOC Quality Measurement & Performance Improvement. Each of these four elements has a number of sub-elements and factors to address the necessary scope and detail of the MOCs. Currently, each of the four SNP model of care elements is valued at 16 points. The aggregate total of all possible points across all elements equals 64, which is then converted to percentage scores based on the number of total points received. CMS provides additional information regarding MOC scoring criteria in Section 20.2.2 of Chapter 5 of the MMCM. In addition to the current element-level minimum benchmark regulatory requirement at § 422.101(f)(3)(iii), SNPs are also required to meet a minimum benchmark score for the aggregate total—otherwise known as the aggregate minimum benchmark. Currently, the aggregate minimum benchmark is 70 percent of the total 64 points. We are proposing to codify this current practice by amending § 422.101(f)(3)(iii) to add that, in addition to the current requirement that all SNPs must meet a minimum benchmark score of 50 percent on each element, each SNP's MOC must meet an aggregate minimum benchmark of 70 percent. As reflected in the proposed revision to paragraph (f)(3)(iii), a SNP's model of care will only be approved if each element of the model of care meets the minimum benchmark and the entire model of care meets the aggregate minimum benchmark.

Second, we are proposing regulation text to address the period of approval for the MOCs that meet the aggregate minimum benchmark. We are proposing to codify at § 422.107(f)(3)(iii)(A) the requirement, from section 1859(f)(5)(B) of the Act, that C–SNP MOCs are annually reviewed and evaluated. Beginning in 2020, under the MOC review process, C–SNPs are only eligible to receive a MOC approval for 1-year and therefore are subject to annual review and approval processes. Specifically, we are proposing at paragraph (f)(3)(iii)(A) to codify that an MOC for a C–SNP that receives a passing score is approved for 1 year. We do not propose to apply the requirement for annual review and approval to the MOCs of all D–SNPs and I–SNPs. Instead, we are proposing, at new paragraph (f)(3)(iii)(B), to codify different approval permits for the MOCs of I–SNPs and D–SNPs that is based on the final score of the MOC on the aggregate minimum benchmark. We are proposing that: (1) an MOC for an I–SNP or D–SNP that receives an aggregate minimum benchmark score of 85 percent or greater is approved for 3 years; (2) an MOC for an I–SNP or D–SNP that receives a score of 75 percent to 84 percent is approved for 2 years; and (3) an MOC for an I–SNP or D–SNP that receives a score of 70 percent to 74 percent is approved for 1 year. This proposed scoring process matches the current process NCQA uses to score initial and annual MOCs. We believe it is prudent to maintain the current scoring process as it has worked well to incentivize improvements in MOCs and strikes a balance with respect to the burden associated with reviews and approvals for all stakeholders by allowing higher scoring MOCs remain in place longer.

Third, we are proposing a new paragraph (f)(3)(iii)(C) to provide an opportunity for a SNP to cure deficiencies in its MOC if the MOC fails to meet the minimum element benchmark or the aggregate minimum benchmark when reviewed and scored by NCQA. Currently, the review and evaluation process includes a second opportunity to submit an initial or renewal MOC, known as ''the cure process.'' Regardless of the final score by NCQA of an MOC resubmitted using the cure process (provided the MOC has the minimum scores to be approved), SNPs that need to use the cure process to reach a passing aggregate minimum and/or minimum element benchmark score will receive only a 1-year approval under this proposal. This policy provides added incentive for SNPs to develop and submit comprehensive and carefully considered MOCs for initial NCQA approval and rewards those SNPs that have demonstrated ability to develop quality MOCs without requiring additional time. We are proposing that the opportunity to cure deficiencies in the MOC is only available once per scoring cycle for each MOC. Under this proposal, a MA organization that fails to meet either the minimum element benchmark for any MOC element or the aggregate minimum benchmark for the entire MOC after having an opportunity to cure deficiencies will not have its MOC approved. MOCs that do not receive NCQA approval after the cure review will not have a third opportunity for review. As a result, the SNP(s) that use that MOC would need to be nonrenewed by the MA organization or terminated by CMS for failure to meet a necessary qualification for SNPs.

We reiterate that this proposal would maintain the current scoring criteria and review process. We believe this proposal creates no additional burden to SNPs, as current MOCs are evaluated based on this criterion already. We welcome comment on the codification of existing MOC scoring requirements for SNPs. These new regulations would be applicable for MOCs reviewed for contract year 2024 and we will continue our current practice pending a final rule.

2. Amending SNP MOCs After NCQA Approval

CMS is proposing to codify current policies and procedures for an MA organizations to amend its MOCs after NCQA approval. CMS has labeled this the ''off-cycle MOC submission process.'' CMS has acknowledged in the past that in order to more effectively address the specific needs of its enrollees, a SNP may need to modify its processes and strategies for providing care during the course of its approved MOC timeframe; CMS announced a process for SNPs to submit MOC changes for review in the CY 2016 Final

[155] The full MOC PRA package can be found here: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10565.*

Call Letter.[156] Currently, a D–SNP or I–SNP that decides to make substantive revisions to their existing approved MOC may submit a summary of their off-cycle MOC changes, along with the red-lined MOC, in the Model of Care module in HPMS for NCQA review and approval. Substantive revisions are those that have a significant impact on care management approaches, enrollee benefits, and/or SNP operations. MOC changes are at the discretion of the applicable MA organization offering the SNP and it is the responsibility of the MA organization to notify CMS of substantive changes and electronically submit their summary of changes to their MOC in HPMS. Beginning with CY 2020, C–SNPs are required to submit MOCs annually, and thus, their MOCs receive approvals for a period of one-year. Upon implementation the annual review and approval of C–SNP MOCs, C–SNPs were not permitted to submit a revised MOC through an off-cycle submission.

At the time of the CY 2016 Final Call Letter, based on our previous experience with the small number of SNPs seeking to amend their MOCs, we expected that mid-cycle amendments to MOCs would be relatively rare and CMS did not anticipate that the off-cycle process would result in a higher incidence of such MOC changes. We believed that only relatively unusual circumstances would require SNPs to make changes to their MOCs that are so significant that notification to CMS and review of the changes to the MOC would be warranted. However, CMS and NCQA have seen the number of off-cycle MOC submissions steadily rise over the past four years and plans have expressed frustration and confusion over what plan changes merit or require submission to NCQA for an off-cycle approval. This proposed rule is intended to address stakeholder feedback regarding the off-cycle review process and to mitigate the SNP community's concerns regarding continued plan burden in this area.

In general, CMS intends the MOC review and approval process to include an MA organization's submission of a MOC only in the following scenarios: the MA organization seeks to offer a new SNP; the MA organization's SNP's MOC approval period ends; or CMS deems revision and resubmission of the MOC necessary to ensure compliance with the applicable standards and requirements, such as a change in applicable law or when CMS discovers a violation. For the last scenario, an off-cycle MOC submission may be necessary if during an audit, it appears that the MOC (including in practice as the SNP applied the MOC) is not meeting applicable standards, then CMS may ask the SNP to correct and resubmit the MOC. Other examples include regulatory changes or when a State Medicaid agency requires changes to the MOC of a D–SNP to meet State-specific requirements. In order to ensure a stable care management process and to ensure appropriate oversight by CMS of SNPs and their operation, SNPs may not implement any changes to a MOC until NCQA has approved the changes. Based on our experience, additional situations may justify the submission of a revised MOC for review and approval. This proposal would establish when an MA organization may submit updates and corrections to its approved MOC.

First, we are proposing to codify the off-cycle process at § 422.101(f)(3)(iv). We propose that MA organizations offering SNPs that need to revise their MOC mid-cycle during their MOC approval period may submit the revised MOC for review by NCQA at specific times. CMS has historically restricted the period that SNPs can submit an off-cycle submission from June 1st to November 30th of any contract year, which is meant to allow for the efficient and prudent administration of the annual initial and review MOC process—with the exception of C–SNPs who are prohibited from submitting off-cycle submissions because of the requirement that plans submit their MOC annually. However, CMS has also allowed SNPs to submit off-cycle MOCs outside of this window when CMS deems it necessary to ensure the SNP or its MOC was meeting statutory or regulatory requirements, guarantee the safety of enrollees, or meet State Medicaid requirements. We propose to maintain this process and codify it at § 422.101(f)(3)(iv)(A). We propose that SNPs may submit updates and corrections to their NCQA-approved MOC between June 1st and November 30th of each calendar year or when CMS deems it necessary to ensure compliance with applicable standards and requirements. We intend the phrase ''applicable standards and requirements'' to encompass the situations described here in the preamble or similar situations where a potential or existing violation needs to be addressed. To ensure consistent application of this standard and demonstrate our intent that these be limited situations where a revision is truly necessary, the proposed regulation text is clear that CMS will make this determination and provide directions to the MA organization. If an MA organization believes that this standard in which revision is necessary to ensure compliance by the SNP and its MOC, we anticipate that the MA organization will contact CMS for guidance and approval to submit a revision.

Since the beginning of the off-cycle submission process, CMS has attempted to provide guidance clarifying which MOC changes require submission to CMS and how SNPs should submit their MOC changes to CMS. We have said in the past that SNPs that make significant changes to their MOCs must submit (in HPMS) a summary of the pertinent modifications to the approved MOC and a redlined version of the approved MOC with the revisions highlighted. Given the level of questions we have received over the years regarding what constitutes a significant change, we are proposing to codify a list of reasons for when a SNP must use an off-cycle submission of a revised MOC for review and approval. Proposed § 422.101(f)(3)(iv)(B) provides that an MA organization must submit updates or corrections to a SNP's MOC to reflect the following:

- Changes in policies or procedures pertinent to:
  - ++ The health risk assessment (HRA) process;
  - ++ Revising processes to develop and update the Individualized Care Plan (ICP);
  - ++ The integrated care team process;
  - ++ Risk stratification methodology; or
  - ++ Care transition protocols;
- Target population changes that warrant modifications to care management approaches or changes in benefits. For example, we intend this to include situations like adding Diabetes to a Cardiovascular Disease and Congestive Heart Failure C–SNP;
- Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related SNP operations. For example, changes in Medicaid services covered by a HIDE SNP or FIDE SNP through its companion Medicaid managed care plan or changes in Medicaid policy (such as benefits or eligibility) that require changes to an ICP for coordinating Medicare and supplemental benefits with the new Medicaid policy;
- Changes in level of authority or oversight for conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel);

[156] See *https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2016.pdf.*

• Changes to quality metrics used to measure performance.

The proposed regulation text does not include immaterial examples of the type and scope of MOC policy changes that may be made by an MA organization to the SNP's approved MOC without any review or approval by CMS or NCQA. Changes that do not need to be submitted through HPMS include:

• Changes in legal entity, parent organization, and oversight (novation/mergers, changes to corporate structure);

• Changes to delegated providers and agreements;

• Changes in administrative staff, types/level of staff that do not affect the level of authority or oversight for personnel conducting care coordination activities;

• Updates on demographic data about the target population;

• Updates to quality improvement metric results and technical quality measure specification updates;

• Additions/deletions of specific named providers;

• Grammatical and/or non-substantive language changes; and

• For D–SNPs, minor changes to Medicaid benefits.

Under this proposal, we are adding a requirement to a new subparagraph D under § 422.101(f)(3)(iv) that SNPs may not implement any changes to a MOC until NCQA has approved the changes. In addition, NCQA will continue to review the summary of changes and a redlined copy of the revised MOC submitted in HPMS to verify that the revisions are consistent with the previously detailed list of applicable submissions and in line with acceptable, high-quality standards, as included in the original, approved MOC. The revised MOCs will not be rescored. Further, the MOC's original approval period (that is, 1-year or multi-year) will not be modified as a result of NCQA's approval of the changes. We propose to codify this policy at § 422.101(f)(3)(iv)(E), which provides that the successful revision of the MOC under proposed (f)(3)(iv) does not change the MOC's original period of approval by NCQA. Therefore, changes made to MOC cannot be used to improve a low score. We anticipate that the current procedures and documentation processes will continue; such procedures and operational practices do not need to be in regulation text. CMS may change procedures as necessary (for example, use of HPMS as the system for submission, the mechanism for providing notice to MA organizations of the review of the MOC initially or any revisions, etc.). We intend that the current procedures will continue for NCQA reviewers to designate the summary as ''Acceptable'' or ''Non-Acceptable,'' and enter the findings in the HPMS character text box. Similarly, we will continue the current process in which a system-generated email is sent to the designated SNP Application Contact and the MA Quality Contact, as well as to the individual who submitted the revised MOC summary. Lastly, we are proposing under § 422.101(f)(3)(iv)(F) to codify existing operational practices with respect to off-cycle submissions by C–SNPs. Currently, C–SNPs are prohibited from submitting off-cycle MOC submissions, as all C–SNPs submit MOCs annually as required under section 1859(f)(5)(B)(iv) of the Act. We are proposing to codify that C–SNPs are prohibited from submitting an off-cycle MOC submission except when CMS requires an off-cycle submission to ensure compliance with the applicable regulations. C–SNPs must wait until the annual MOC submission period to make changes to their MOC.

SNPs have one opportunity to correct (''cure'') deficiencies, as noted in our proposed rule § 422.101(f)(3)(iii)(C) to confirm that the revised MOC is consistent with the standards outlined in the original MOC. If NCQA determines that revisions to an initial or renewal MOC, as delineated in the MOC summary, do not reflect the quality standards as demonstrated by the original MOC and its associated score/approval period, the SNP will be notified via email with a ''Non-Acceptable'' determination and a list of all deficiencies. If the summary and redlined version is not acceptable after the second review, the SNP must continue implementing its approved MOC without any revisions for the remainder of its MOC approval period. The proposed MOC off-cycle cure process at § 422.101(f)(3)(iv) differs from the review and scoring process being codified § 422.101(f)(3)(iii). The review process employed under § 422.101(f)(3)(iii) provides a one-time cure process. Likewise, the cure process proposed (and under current operational use by NCQA) would allow D–SNPs and I–SNPs to resubmit a single revised off-cycle submission or cure until the end of the Off-cycle submission period to an Off-cycle MOC that was deemed unacceptable during the off-cycle review process. We are proposing to codify this policy of a single cure opportunity during the off-cycle time period under a new paragraph at § 422.101(f)(3)(iv)(G)

We have also found that SNPs have sought to modify an initial or renewal MOC shortly after NCQA approval and before the MOC has gone into effect. We have generally rejected these submissions because the MOC has yet to go into effect. We will continue to prohibit an off-cycle submission until the approved MOC has gone into effect. For example, if NCQA approved a SNP's MOC on April 1, 2022, the plan would be prohibited from submitting an off-cycle submission until the effective date of the MOC, which would be January 1, 2023.

In order clarify this process, we are proposing to codify this guidance at § 422.101(f)(3)(iv)(C). We propose that NCQA will only review off-cycle submissions after the start of the effective date of the current MOC unless it is deemed necessary to ensure compliance with the applicable regulations or State Medicaid agency requirements for D–SNPs. Finally, we reiterate that we still believe that off-cycle submissions to substantively revise an MOC should be a rare occurrence rather than an eventuality. We believe that these proposed processes and procedures will make certain that CMS and NCQA are apprised of up-to–date information regarding the MOC; strengthen our ability to adequately monitor the approved MOCs; and guarantee that SNPs continue to provide high quality care to enrollees. We seek comment on the codification of the current off-cycle MOC submission process.

The proposed regulations described here reflect and would codify current policy and procedures. While this proposed rule as a whole is generally intended to be applicable beginning with contract year 2024, we intend to continue our current policy as reflected here. We also believe the following proposed changes carry no burden. This proposal is a codification of previously issued subregulatory guidance in Chapter 5 and other CMS transmittals to impacted MA organizations. More importantly, the current proposed codification is already captured under the PRA package ''Initial and Renewal Model of Care Submissions, and Off-cycle Submission of Summaries of Model of Care Changes (CMS–10565, OMB 0938–1296). As part of the PRA approval package, CMS reviews public comments directed towards the initial and renewal MOC process, MOC trainings, and the off-cycle MOC submission system. Again, the burden effort associated with this proposed rule covering the latter items is captured in the currently approved MOC PRA.

Based on our experience monitoring SNPs and engaging in the process for review and approval of MOCs, we believe plans are following the our

current subregulatory guidance and therefore no further burden is imposed by codifying these standards.

G. Clinical Trial-Related Provisions (§§ 422.101 and 422.109)

MA plans must cover Medicare Part A and Part B benefits, excluding hospice, kidney acquisitions for transplant, and certain changes in benefits due to a National Coverage Determination (NCD) or a legislative change. We are proposing to adopt regulations regarding MA coverage of clinical trials covered by Medicare to ensure clarity on these coverage rules for MA plans. These coverage rules implement section 1852 of the Act and are within our rulemaking authority for the MA program. These proposals generally codify guidance currently specified in section 10.7 of Chapter 4 of the Medicare Managed Care Manual for clinical trials covered under National Coverage Determination (NCD) 310.1; A and B investigational device trials (A–B IDE); and National Coverage Determinations with coverage with evidence development (NCD–CED).

1. Clinical Trials Under National Coverage Determination 310.1

Clinical trials may include some items and services that would not be covered by Medicare, absent the trial. For clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD) (NCD manual, Pub. 100–03, Part 4, section 310), longstanding CMS policy has been that traditional Medicare (that is, the Medicare FFS program) covers the routine costs of qualifying clinical trials for all Medicare enrollees who volunteer to participate in the approved trial, including those enrolled in MA plans. CMS has discussed this policy in several Advance Notices and Rate Announcements, including the advance notices of methodological changes in Part C payments issued for 2004, 2007, 2008, 2009, 2011, 2017, and 2019, and in the announcements of capitation rates and payment policies for Part C in 2009, 2011, 2012, and 2017. NCD 310.1 is the current statement of the Medicare coverage of routine costs associated with clinical trial participation. As specified in the NCD, routine costs associated with a clinical trial include:

- Items or services that are typically provided by Medicare absent a clinical trial (for example, conventional care);
- Items or services required solely for the provision of the investigational item or service (for example, administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

Although MA plans must follow all NCDs, section 1852(a)(5) of the Act, which CMS has implemented in § 422.109(b), provides that if an NCD or new legislative benefit introduced in the middle of a plan year is considered a significant cost as determined by the Office of the Actuary, MA plans are not responsible for coverage until the cost to provide the new benefit is calculated into the plan's payment rate. CMS has previously determined, as discussed in the CY 2019 Advance Notice,[157] that the multiple clinical trials covered under NCD 310.1 trigger the significant cost threshold. Therefore, traditional Medicare has covered the Medicare-covered routine costs of clinical trials that are covered under NCD 310.1 for MA enrollees. To ensure continued clarity and transparency for this longstanding policy, discussed in section 10.7.1 of Chapter 4 of the Medicare Managed Care Manual, we are proposing to codify this policy by adding new § 422.109(e). In § 422.109(e)(1), we propose to codify that traditional Medicare is responsible for coverage of routine costs of qualifying clinical trials for MA enrollees for clinical trials covered under the Clinical Trials National Coverage Determination 310.1 and all reasonable and necessary items and services used to diagnose and treat complications from participating in clinical trials.

Deductibles and MA Responsibility for Differences in Cost-Sharing

Traditional Medicare pays for all routine costs of clinical trials for MA enrollees and, as explained in the CY 2011 Rate Announcement,[158] MA enrollees do not pay the traditional Medicare Part A and B deductibles when the traditional Medicare pays the Medicare-covered costs associated with the clinical trial.[159] In § 422.109(e)(2), we propose to codify this policy that MA enrollees participating in clinical trials are not subject to Part A and B deductibles.

MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services. We propose to codify this requirement for MA plans to pay the difference between traditional Medicare and plan's cost sharing in § 422.109(e)(3). We also propose in § 422.109(e)(4) to codify that the enrollee's in-network cost-sharing portion must be included in the plan's maximum out-of-pocket (MOOP) calculation. As the clinical trial costs within the scope of NCD 310.1 are covered by Part A and/or Part B, these are basic benefits within the scope of the MOOP requirements in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) but for clarity we are proposing to codify at § 422.109(e)(4) the requirement that the enrollee's in-network cost-sharing must be included in the plan's MOOP calculation. In requiring MA organizations to provide in-network cost sharing for clinical trial services, CMS is requiring that MA plan members have coverage for clinical trial services that is consistent with coverage they have for all other Medicare Part A and Part B services. In paragraph (e)(5), consistent with our guidance in section 10.7.1 of Chapter 4 of the Medicare Managed Care Manual, we would specify that MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial under NCD 310.1. This protection is necessary in order to ensure that MA enrollees have access to and coverage of clinical trials within the scope of NCD 310.1 to the same extent as Medicare beneficiaries enrolled in the traditional Medicare program. While MA plans are responsible for covering any differences in cost-sharing between traditional Medicare and MA plan in-network costs for services in the same category, traditional Medicare, through the MACs, is responsible for all other costs included in clinical trials within

[157] The Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter discusses the clinical trial coverage policy for the MA program on pages 23–23 and is available at this link: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf.*

[158] The Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter addresses this in a response to a comment on page 20–21 and is available at the following link: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2011.pdf.*

[159] In addition, the See page 31 of the MA Payment Guide for Out of Network Payments, page 31, addresses this topic. The guide is available at the following link: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf.*

the scope of NCD 310.1. Finally, in accordance with § 422.109(c)(2), CMS requires MA organizations to provide coverage for: 1) services to diagnose conditions covered by clinical trial services; 2) most services furnished as follow-up care to clinical trial services; and 3) services already covered by the MA organization. Because § 422.109(c) adequately addresses how MA organizations are required to cover certain benefits and costs even when the traditional Medicare program pays for changes in benefits as a result of an NCD or legislative change, we do not believe that additional regulation text is necessary to apply those rules in the context of NCD 310.1.

2. A–B Investigational Device Exemption Trials

The regulation at § 405.211 specifies Medicare coverage of Category A and B investigational device exemption (IDE) studies. Providers of device trials must submit approval for the devices from the FDA, as part of their application to CMS for approval of a trial. Once a trial has been approved by CMS, it is listed on the CMS website. In addition to including assessment of devices, IDE trials differ from clinical trials under NCD 310.1, as they are not covered as a result of an NCD nor are they subject to a significant cost assessment. As a result, MA organizations are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered under traditional Medicare. This is part of the MA organization's obligation to cover the items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B for their enrollees under section 1852 of the Act.

MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. An MA plan is also responsible for coverage of CMS-approved Category B devices. While CMS will cover routine care items and services, it will not approve coverage of Category A devices themselves because they are considered experimental and excluded from coverage under § 405.211(a). As with other benefits for which it is responsible for coverage, an MA plan may apply utilization management, including prior authorization, consistent with § 422.4(a)(1)(ii).

Section 10.7.2 of Chapter 4 of the Medicare Managed Care Manual addresses this policy. In order to clarify this scope of required coverage for MA plans and avoid any inadvertent confusion between the coverage requirements associated with clinical trials under NCD 310.1, we propose to add § 422.109(f) to specify MA plan coverage of the routine items and services, including the Category B IDE device and related items and services in the context of a Category A and B IDE studies, that are covered by Medicare under §§ 405.211(a) and (b).

3. National Coverage Determinations With Coverage With Evidence Development

Section 1852(a)(1) of the Act requires MA plans to cover all Medicare Part A and Part B benefits, subject to limited exclusions. One of those exclusions relates to new NCDs that result in significant cost increases, making it clear that benefits covered under an NCD are included in what MA plans must cover. In addition, § 422.101(b)(1) explicitly requires MA plans to cover NCDs. (See section III. E. of this document, Utilization Management Requirements, for more information on CMS' proposal to address MA plan coverage obligations.) NCDs generally provide guidance about coverage of new benefits, update an existing benefit or, in some cases, specify that a procedure or service is not covered. As with other Part A and B benefits (aside from hospice and the cost of kidney acquisition for transplant), MA plans must cover NCDs. This is true for NCDs that also have a trial or registry component that is required as part of the coverage, which is explained in section 10.7.3 of Chapter 4 of the Medicare Managed Care Manual. This is referred to as ''coverage with evidence development'' (CED), as authorized under the statute at 1862(a)(1)(E). CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of CMS approved clinical studies or with the collection of additional clinical data (for example, registry). A list of NCD–CEDs with the coverage protocol for each is available at: *https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development.*

We are merely reiterating here that MA plans must cover NCDs with CED and are not proposing a change in policy. We solicit comment whether additional regulations are needed to address NCDs with CED; we believe that § 422.101(b) is sufficient that these NCDs are within the scope of the traditional Medicare benefits that MA plans must cover and that additional regulations are unnecessary. MA plans may apply utilization management, including prior authorization, to the Medicare benefits covered under these NCDs, consistent with § 422.4(a)(1)(ii) of the MA program regulations.

Significant Cost

In cases of a new NCD or legislative change in benefits, CMS determines, consistent with § 422.109(b), whether the benefit or service is a significant cost to MA plans. CMS is including this discussion here to make clear that significant cost requirements apply to all new NCDs, that is, that the significant cost assessment includes NCDs with CED. The thresholds for significant cost are specified in §§ 422.109(a)(1) and (a)(2). The assessment generally applies to each NCD or legislative change in benefits that occurs after the rate announcement for a contract year such that the change in costs was not incorporated into the capitation rates for the contract year. Costs are estimated for a particular NCD or legislative change in benefits so the thresholds specified in §§ 422.109(a)(1) and (a)(2) apply to each NCD or legislative change in benefits rather than to the aggregate number of such changes over the course of a contract year.

H. Required Notice for Reinstatements Based on Beneficiary Cancellation of New Enrollment (§§ 422.60 and 423.32)

Sections 1851(c)(1) and 1860D–1(b)(1) of the Act establish the enrollment, disenrollment, termination, and change in coverage processes for MA and PDP plans. In the June 1998 interim final rule, we established the M+C (now MA) enrollment process (63 FR 34968). These requirements are codified in regulation at § 422.60. In the January 2005 Part D final rule, we established the PDP enrollment process (70 FR 4193). These requirements are codified in regulation at § 423.32.

Section 1851(g)(3)(B)(i) of the Act provides that MA plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums on a timely basis; likewise, section 1860D–1(b)(1)(B)(v) of the Act directs the Secretary to use rules similar to (and coordinated with) the rules for an Medicare Advantage plan established under section 1851(g) of the Act. CMS has previously codified this process of optional disenrollment from an MA plan or PDP for failure to pay monthly premiums at §§ 422.74(d) and 423.44(d), as well as requirements for mandatory disenrollment for individuals who fail to pay the Part D Income Related Monthly Adjustment Amount (Part D–IRMAA), where applicable, at § 423.44(e). In addition, CMS has previously codified the ability for MAOs and PDP sponsors to reinstate for good cause an individual who is disenrolled

for failure to pay plan premiums (at §§ 422.74(d)(1)(v) and 423.44(d)(1)(vi)) or the Part D–IRMAA (at § 423.44(e)(3)).

However, an individual's enrollment can also be reinstated if their enrollment in another plan is subsequently canceled within timeframes established by CMS. We established at § 422.66(b)(1) that an individual is disenrolled from their MA plan when they elect a different MA plan; likewise, at § 423.36(a), an individual is disenrolled from their PDP plan when they enroll in a different PDP plan. Sub-regulatory guidance requires MA and PDP plans to provide notification of enrollment reinstatement based on a beneficiary's cancellation of a new enrollment in a different plan. This guidance is currently outlined in the Part C and Part D sub-regulatory guidance found in section 60.3.2 of Chapter 2 of the Medicare Managed Care Manual and section 60.2.2 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, respectively.

To provide transparency and stability for stakeholders, we are proposing at new §§ 422.60(h) and 423.32(h) to require that MA and PDP plans must notify an individual when the individual's enrollment is reinstated due to the individual's cancellation of enrollment in a different plan. A reinstatement is generally not allowed if the individual intentionally initiated a disenrollment and did not cancel the disenrollment prior to the disenrollment effective date. However, when a beneficiary is automatically disenrolled from their plan because of enrollment in a new plan but then cancels the request to enroll in the new plan within established timeframes, the associated automatic disenrollment from the previous plan becomes invalid. Therefore, the beneficiary's enrollment in the previous plan needs to be reinstated and CMS systems will attempt to automatically reinstate enrollment in the previous plan. Consistent with notification requirements in similar enrollment scenarios, we propose that the organization from which the individual was disenrolled send the member notification of the enrollment reinstatement within 10 days of receipt of Daily Transaction Reply Report (DTRR) confirmation of the individual's reinstatement. The reinstatement notice would include confirmation of the individual's enrollment in the previous plan with no break in coverage, plan-specific information as needed, and plan contact information.

These proposed changes represent the codification of longstanding guidance. Based on infrequent complaints and questions from plans and beneficiaries related to current requirements, we conclude that the requirements have been previously implemented and are currently being followed by plans. There is also no impact to the Medicare Trust Fund.

I. Part D Plan Failure To Submit Disenrollment Timely (§ 423.36)

Section 1860D–1(b) of the Act establishes the disenrollment process for Part D eligible individuals in prescription drug plans. This section of the Act grants the Secretary the authority to establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. In 2005, the implementing regulations at 70 FR 4525 established the voluntary disenrollment process for Part D prescription drug plans. These requirements are codified in regulation at § 423.36 and require the Part D sponsor to ''submit a disenrollment notice to CMS within timeframes CMS specifies.''

As previously noted, section 1860D–1(b)(1)(B) of the Act directs the Secretary to adopt enrollment rules ''similar to (and coordinated with)'' the rules established under Part C. In 1998 implementing regulations for Part C, CMS provided that if a ''Medicare + Choice'' (M+C) organization, later known as an MA organization, fails to submit the correct and complete notice of disenrollment, the M+C organization must reimburse the Health Care Finance Administration (the predecessor to CMS), for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely (63 FR 35071). This requirement was codified at § 422.66(b)(4) and has remained in place for MA organizations. Current Part D regulations do not impose requirements for Part D sponsors that fail to submit the transaction notice to CMS timely. However, longstanding CMS policy has provided that the PDP sponsor must submit disenrollment transactions to CMS in a timely manner, as described in section 50.4.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. When a valid request for disenrollment has not been communicated to CMS successfully within the required timeframes, a retroactive disenrollment can be submitted to CMS. If the retroactive disenrollment request is approved, the PDP sponsor must return any premium paid by the member for any month for which CMS processed a retroactive disenrollment, and CMS will retrieve any capitation payment for the retroactive period for an approved request for retroactive disenrollment, as described in section 60.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. To provide transparency and consistency for stakeholders, and align the Part D regulation with the requirements for MA organizations, we propose to codify CMS's longstanding sub-regulatory guidance by amending § 423.36 to add a new paragraph (f) to reflect that if the Part D sponsor fails to submit a disenrollment notice to CMS timely as required by § 423.36(b)(1), such that the Part D sponsor receives additional capitation payments from CMS, the Part D sponsor must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

This proposal is a codification of longstanding Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. As these policies have been previously implemented and are currently being followed by plans, we conclude that there is no additional paperwork burden. All information impacts related to our collection of disenrollment requests have already been accounted for under OMB control number 0938–0964 (CMS–10141).

J. Codify Existing Policy ''Incomplete Disenrollment Requests'' (§§ 422.66 and 423.36)

Section 1851(c)(2)(B) of the Act provides that an individual who elects an MA plan and then chooses to terminate such election can do so by submitting a request to the MA organization. In addition, section 1860D–1(b)(1)(B)(ii) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall use rules similar to (and coordinated with) the rules for an Medicare Advantage (MA)—formerly M+C—plan established under section 1851(c) of the Act.

The June 1998 final regulation established the process for individuals to voluntarily disenroll from an MA plan. This process is codified at § 422.66(b). Specifically, at § 422.66(b)(2) we provide that a disenrollment request is considered to have been made on the date the disenrollment request is received by the MA organization. Once received, the MA organization is required to send the disenrollment notice to CMS and a copy to the enrollee which informed the enrollee of any lock-in requirements of the plan that apply until the effective date of disenrollment. This process is

codified at § 422.66(b)(3), including the requirement that the MA plan must file and retain the disenrollment request as specified in CMS instructions.

In 2005, CMS issued implementing regulations establishing disenrollment procedures for Part D plans, whereby an individual elects to voluntarily disenroll from the Part D plan, and also established the requirements imposed upon the Part D sponsor as a result of that disenrollment request (63 FR 35071). These requirements were codified at § 423.36.

However, §§ 422.66(b) and 423.36 do not address what plans should do in the event that they receive incomplete disenrollment requests. CMS has historically provided the procedural steps for plans to address incomplete disenrollment requests, in section 50.4.2, Chapter 2 of the Medicare Managed Care Manual and section 50.4.2, Chapter 3 of the Medicare Prescription Drug Benefit Manual, including providing that when the disenrollment request is incomplete, plans must document its efforts to obtain information to complete the request; and if any additional information needed to make the disenrollment request ''complete'' is not received within prescribed timeframes, the plan must deny the disenrollment request.

To provide transparency and stability for stakeholders about the MA and Part D programs and about the requirements applicable to requests for voluntary disenrollment from MA and Part D plans, we are proposing to codify CMS's longstanding policies in this area at new paragraphs § 422.66(b)(6) and 423.36(d) that a disenrollment request is considered to be incomplete if the required but missing information is not received by the MA plan or Part D sponsor within the specified timeframes in proposed §§ 422.66(b)(3)(v)(C) and 423.36(b)(4)(iii), as described in this rule. We are also proposing at new paragraphs §§ 422.66(b)(3)(v) and 423.36(b)(4) that if the disenrollment request is incomplete, the plan must document its efforts to obtain information to complete the election. Plans would be required to notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request. For incomplete disenrollment requests received by plan sponsors during the annual election period (AEP), we are proposing information to complete the request must be received by December 7, or within 21 calendar days of the plan sponsor's request for additional information, whichever is later. For all other election periods, we are proposing that required information must be received by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later. Finally, we are proposing that if any additional information needed to make the disenrollment request complete is not received within these timeframes, the disenrollment request must be denied.

We are codifying longstanding guidance with these changes. All information impacts related to the procedural steps plans must take to address incomplete disenrollment requests have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D. Based on infrequent questions from MA organizations and Part D plan sponsors as these requirements have been previously implemented and are currently being followed by plans, we conclude that these updates do not add to the existing disenrollment process and we do not believe there is any additional paperwork burden.

K. Reinstatement of Enrollment for Good Cause (§§ 417.460, 422.74 and 423.44)

As previously noted, sections 1851(g)(3)(B)(i) and 1860D–1(b)(1)(B)(v) of the Act provide that MA and Part D plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums on a timely basis. In addition, section 1860D–13(a)(7) of the Act mandates that individuals with higher incomes pay an additional premium, the Part D IRMAA, for the months in which they are enrolled in Part D coverage.

Consistent with these sections of the Act, the MA and Part D subpart B regulations set forth our requirements with respect to involuntary disenrollment procedures under §§ 422.74 and 423.44, respectively. Pursuant to §§ 422.74(d)(1)(i) and 423.44(d)(1), an MA or Part D plan that chooses to disenroll beneficiaries for failure to pay premiums must be able to demonstrate to CMS that it made a reasonable effort to collect the unpaid amounts by notifying the beneficiary of the delinquency, providing the beneficiary a period of no less than two months in which to resolve the delinquency, and advising the beneficiary of the termination of coverage if the amounts owed are not paid by the end of the grace period. Further, as outlined in § 423.44(e), CMS involuntarily disenrolls individuals from their Part D coverage for failure to pay Part D–IRMAA following an initial grace period of 3 months.

Current regulations at § 417.460(c) specify that an HMO or competitive medical plan (cost plan) may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. While there is not a grace period parallel to the grace period required by the MA and Part D regulations, the requirements for cost plans are otherwise similar. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount and send the enrollee written notice of the disenrollment prior to transmitting the disenrollment to CMS.

The final rule, titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' which appeared in the **Federal Register** on April 15, 2011 (76 FR 21431) amended both the Parts C and D regulations at §§ 422.74(d)(1)(v), 423.44(d)(1), and 423.44(e)(3) regarding involuntary disenrollment for non-payment of premiums or Part D–IRMAA to allow for reinstatement of the beneficiary's enrollment into the plan for good cause. The good cause provision established that CMS can reinstate enrollment of a disenrolled individual's coverage in certain circumstances where the non-payment of premiums was due to a circumstance that the individual could not reasonably foresee and could not control, such as an extended period of hospitalization. In the final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' which appeared in the **Federal Register** on April 12, 2012 (77 FR 22071), we extended the policy of reinstatement for good cause to include beneficiaries enrolled in cost plans in § 417.460(c)(3), thus aligning the cost plan reinstatement provision with the MA and Part D plan provisions. In the final rule titled ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' which appeared in the **Federal Register** on February 12, 2015 (80 FR 7911), we amended § 417.460(c)(3), § 422.74(d)(1)(v), and § 423.44(d)(1)(vi) to permit an entity acting on behalf of CMS, such as an MA organization, Part D sponsor, or entity offering a cost plan, to effectuate reinstatements for beneficiaries disenrolled for nonpayment of plan premium when good cause criteria are met.

To provide transparency to stakeholders, we are proposing to codify our current policy for MA organizations, Part D sponsors, or entities offering cost plans, as set out in sub-regulatory guidance in section 60.3.4 of Chapter 2, Medicare Managed Care Manual, section 60.2.4 of Chapter 3, Medicare Prescription Drug Benefit Manual and section 60.6.3 of Chapter 17–D, Medicare Managed Care Manual, that reinstatement for good cause, pursuant to §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi), will occur only when the individual requests reinstatement within 60 calendar days of the disenrollment effective date and that an individual may make only one reinstatement request for good cause in this 60-day period. Specifically, CMS is proposing to amend §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi) to provide that the disenrolled individual must request reinstatement within 60 calendar days of the disenrollment effective date and has not previously requested reinstatement for good cause during the same 60 day period following the involuntary disenrollment. These proposed changes represent the codification of longstanding guidance. Based on infrequent questions or complaints from plan sponsors and beneficiaries, and a lack of reported instances of noncompliance regarding the 60-day timeframe, as these requirements have been previously implemented and are currently being followed by plan sponsors, we conclude that the proposed changes to the regulatory text will not adversely impact plan sponsors or individuals disenrolled for nonpayment of plan premium who choose to request reinstatement for good cause, nor would the proposed changes have any impact to the Medicare Trust Funds or result in a paperwork burden.

L. Required Notices for Involuntary Disenrollment for Disruptive Behavior (§§ 417.460, 422.74 and 423.44)

Section 1851(g)(3)(B)(ii) of the Act authorizes an MA organization to disenroll individuals that engage in disruptive behavior. Section 1860D–1(b)(1)(B)(v) of the Act generally directs us to establish rules related to enrollment, disenrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851(g) of the Act. Section 1876 of the Act sets forth the rules for Medicare cost plan contracts with HMOs and competitive medical plans (CMPs). In implementing regulations which appeared in the **Federal Register** on September 1, 1995 (60 FR 45678), we established at § 417.460(e) the basis for HMOs and CMPs to disenroll individuals for disruptive, unruly, abusive, or uncooperative behavior. In implementing regulations which appeared in the **Federal Register** on June 26, 1998 (63 FR 35071), we established at § 422.74 the conditions for MA organizations (referred to M+C organizations at the time) to disenroll individuals for disruptive behavior. Additionally, the regulations established the requirement for a final notice to the beneficiary of the submission of the disenrollment, which applies to disruptive behavior disenrollments, at § 422.74(c). The optional basis for disenrollment for disruptive behavior was established at § 422.74(b)(1)(ii). The general standards defining disruptiveness were established in § 422.74(d)(2).

In January 2005, we published a final rule that revised the definition for disruptive behavior at § 422.74(d)(2) (70 FR 4718), with the purpose of creating an objective definition that did not use the previously subjective terms such as ''unruly'' or ''abrasive.'' The current, objective definition from the January 2005 MA final rule both defines disruptive behavior and establishes the required process for an MA plan to request disenrollment of a disruptive individual. In January 2005 we also published the Part D implementing regulation (70 FR 4525), where we established the conditions for a PDP sponsor to disenroll an individual for disruptive behavior. We established the basis for optional disenrollment for disruptive behavior at § 423.44(b)(1)(ii). We also established the definition of disruptive behavior and disenrollment process as it exists currently at § 423.44(d)(2). In the January 2005 Part D final rule, we also established the requirement for a final notice of the submission of the disenrollment transaction, which applies to disruptive behavior disenrollments, at § 423.44(c).

Under CMS's current MA and Part D regulations, disruptive behavior is defined as behavior by the plan enrollee that substantially impairs the plan's ability to arrange for or provide services for the individual or other plan members (§§ 417.460(e)(1); 422.74(d)(2)(i); 423.44(d)(2)(i)). The process for disenrolling an enrollee for disruptive behavior requires approval by CMS before the disenrollment may be submitted (§§ 417.460(e)(5); 422.74(d)(2)(v); 423.44(d)(2)(v)). MA organizations, Part D sponsors, and cost plans must make serious efforts to resolve the problem considering any extenuating circumstances; for MA organizations, cost plans, and Part D sponsors this includes providing reasonable accommodations for those beneficiaries with mental or cognitive conditions (§§ 417.460(e)(2) and (3); 422.74(d)(2)(iii); 423.44(d)(2)(iii)). MA organizations, Part D sponsors, and cost plans must also document the beneficiary's behavior and the plan's own efforts to resolve the issue, and this record must be submitted to CMS before disenrollment can be approved (§§ 417.460(e)(4) and (5); 422.74(d)(2)(iv) and (v); 423.44(d)(2)(iv) and (v)). The current definition of disruptive behavior in §§ 417.460(e)(1), 422.74(d)(2), and 423.44(d)(2) served as the basis for CMS's current sub-regulatory guidance found in Chapter 2, section 50.3.2, of the Medicare Managed Care Manual and Chapter 3, section 50.3.2, of the Medicare Prescription Drug Benefit Manual and Chapter 17D, section 50.3.3, of the Medicare Managed Care Manual. In guidance, we outline member notices that an MA organization, Part D sponsor, and cost plans must send before requesting permission from CMS to involuntarily disenroll the member.

To provide transparency to stakeholders and stability as to the operation of the program, we are proposing to codify current policy for MA, Part D, and cost plan notices during the disenrollment for disruptive behavior process. These notices provide the beneficiary with a warning of the potential consequences of continued disruptive behavior. In a new proposed paragraph, a § 422.74(d)(2)(vii), we propose to codify existing policy currently set out in sub-regulatory guidance regarding MA plan notices prior to a member disenrollment for disruptive behavior. To request approval of a disenrollment for disruptive behavior, an MA organization would be required to provide two notices: (1) an advance notice, informing the plan member that continued disruptive behavior could lead to involuntary disenrollment; and (2) a notice of the plan's intent to request CMS permission to disenroll the member, sent at least 30 days after the advance notice to give the member an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 422.74(c). We are also proposing to revise the existing requirement at § 422.74(d)(2)(iii) that plans inform the individual of the right to use the plan's grievance procedures, to clarify that this information should be conveyed as part of the notices described in new paragraph (d)(2)(vii). Additionally, as proposed in additions to § 422.74(d)(2)(iv), the plan would be

required to submit dated copies of these required notices to CMS along with the other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

At new paragraph § 423.44(d)(2)(viii), we propose to codify existing policy currently set out in subregulatory guidance regarding PDP sponsor notices prior to a member disenrollment for disruptive behavior. To request approval of a disenrollment for disruptive behavior, a PDP sponsor would be required to provide two notices: (1) an advance notice, informing the plan member that continued disruptive behavior could lead to involuntary disenrollment; (2) a notice of intent to request CMS permission to disenroll the member, sent at least 30 days after the advance notice to give the member an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 423.44(c). We are also proposing to revise the existing requirement at § 423.44(d)(2)(iii) that plans inform the individual of the right to use the plan's grievance procedures, to clarify that this information should be conveyed as part of the notices described in new paragraph (2)(d)(viii). Additionally, as proposed in additions to § 423.44(d)(2)(iv), the plan would be required to submit dated copies of these required notices to CMS along with the other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

At § 417.460(e)(7) we propose to codify existing policy guidance currently set out in subregulatory guidance regarding cost plan notices prior to an enrollee disenrollment for cause (disruptive behavior). Current guidance is found in Chapter 17D of the Medicare Managed Care Manual, section 50.3.3. To request approval of a disenrollment for disruptive behavior, an HMO or CMP would be required to provide two notices: (1) an advance notice, informing the enrollee that continued disruptive behavior could lead to involuntary disenrollment; (2) a notice of intent to request CMS permission to disenroll the enrollee, sent at least 30 days after the advance notice to give the member an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 417.460(e)(6). We are also proposing to revise the existing requirement at § 417.460(e)(2) that plans inform the individual of the right to use the plan's grievance procedures, to clarify that this information should be conveyed as part of the notices described in new paragraph (e)(7). Additionally we are proposing in § 417.460(e)(2) that, as part of its efforts to resolve the problem presented by the enrollee, a HMO or CMP must provide reasonable accommodations for individuals with mental or cognitive conditions, including mental illness and developmental disabilities, similar to the existing requirement in the MA and Part D regulations at §§ 422.74(d)(2)(iii); 423.44(d)(2)(iii)). As proposed in § 417.460(e)(4), cost plans would be required to submit dated copies of these required notices to CMS along with other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

We are codifying longstanding guidance with these changes. All information impacts related to the involuntary disenrollment by the plan for disruptive behavior have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D. Based on infrequent questions from MA organizations, Part D, and cost plan sponsors on these notices, as these notice requirements have been previously implemented and are currently being followed by plans, we conclude that these updates do not add to the existing disenrollment process and we do not believe there is any additional paperwork burden.

M. Codification of the Part D Optional Disenrollment for Fraud and Abuse Policy (§ 423.44)

As noted previously, section 1851(g)(3)(B)(ii) of the Act provides that an MA organization may disenroll individuals that engage in disruptive behavior. In 1998, the Part C implementing regulations at 63 FR 35075 separately referred to a different kind of ''disruption'' or ''failure to cooperate'', namely, fraud or abuse on the part of the individual on the enrollment form, or by misuse of the individual's enrollment card. This basis for termination, that is, if the individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card, which was also based on section 1851(g)(3)(B)(ii) of the Act, was codified as a separate paragraph at § 422.74(b)(1)(iii) (63 FR 35075). Regulations also provided a process for disenrollment on this basis, whereby, an M+C organization may disenroll an individual that knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the M+C plan, or intentionally permits others to use his or her enrollment card to obtain services under the M+C plan, as long as a notice of disenrollment is provided as outlined in Federal law. The M+C organization was also required to report the disenrollment to Medicare. This process for disenrollment based on fraud or abuse on the part of the individual was codified at § 422.74(d)(3) (63 FR 35075). Fraud and abuse by the enrollee are treated in the same manner as other forms of disruptive behavior, with the individual being disenrolled into the original Medicare program.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) enacted the Medicare Advantage program, which replaced the M+C program established under title XVIII of the Act, and amended title XVIII of the Act to add a new part D (Voluntary Prescription Drug Benefit Program). Section 1860D–1(b)(1)(B)(v) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall use rules similar to (and coordinated with) the rules for an MA–PD plan established under section 1851(g) of the Act. In 2005, CMS finalized implementing regulations, at §§ 423.44 (b)(1)(ii) and (d)(2), providing that PDP sponsors may disenroll an individual who engages in disruptive behavior and defining the process for disenrollment on this basis (70 FR 4530). However, CMS's 2005 implementing regulations did not include provisions allowing PDP sponsors the ability to disenroll individuals on the basis of fraud or abuse on the part of the individual on the enrollment form, or by misuse of the individual's enrollment card, equivalent to the MA regulations at §§ 422.74(b)(1)(iii) and (d)(3).

Although CMS has adopted and implemented this same basis for optional disenrollment from a Part D plan in sub-regulatory guidance, we are now proposing to codify the policy for optional disenrollment from a Part D plan based on an individual providing fraudulent information on his or her election form or permitting abuse of his or her enrollment card. Our intent is to codify the current policy, as reflected in section 50.3.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. These proposed regulations would also align the rules for Part D plans with the current rules for MA plans for optional disenrollment for an individual who commits fraud or permits abuse of their enrollment card, as provided in the MA regulations at

§ 422.74. Codifying our existing policy will provide transparency and stability for stakeholders about the Part D program.

We are proposing to add a new § 423.44(b)(1)(iii) to codify that if an individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in new paragraph (d)(9) of this section, the Part D plan has the option to involuntarily disenroll the individual. Further, we are proposing to add a new § 423.44(d)(9) to establish the process for optional disenrollment for an individual who commits fraud or permits abuse of their enrollment card. We are proposing to add a new § 423.44(d)(9)(i) to establish a basis for disenrollment for an individual who commits fraud or permits abuse of their enrollment card as provided in §§ 423.44(d)(9)(i)(A) and 423.44(d)(9)(i)(B). We are proposing to establish in § 423.44(d)(9)(i)(A) that a Part D plan may disenroll an individual who knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the Part D plan. We are proposing to establish in § 423.44(d)(9)(i)(B) that a Part D plan may disenroll an individual who intentionally permits others to use his or her enrollment card to obtain drugs under the Part D plan.

We are further proposing to add a new § 423.44(d)(9)(ii) to establish that a Part D plan who opts to disenroll an individual who commits fraud or permits abuse of their enrollment card must provide the individual a written notice of the disenrollment that meets the notice requirements set forth in § 423.44(c) of this section. We are also proposing to add a new § 423.44(d)(9)(iii) to establish that a Part D plan must report to CMS any disenrollment based on fraud or abuse by the individual.

With regard to our Part D optional involuntary disenrollment for fraud and abuse policy, the following change will be submitted to OMB for review under control number OMB 0938–0964 (CMS–10141). We estimate that it will take a Part D plan three hours to capture and retain the required documentation for each occurrence of disenrollment for fraud and abuse. In part, the burden associated with this requirement is the time and effort necessary for a Part D plan to document and retain the documentation that meets the requirements set forth in this section. Based on actual experience, since 2012, there have only been five disenrollments for fraud and abuse. Three of those disenrollments were from MA/MAPD plans, one was from the Limited Income Newly Eligible Transition (LI NET) plan, and one was from a standalone Part D plan. Thus, the burden to Part D plans is negligible and per 5 CFR 1320.3(c) not subject to PRA because it involves less than 10 entities per year. Nonetheless, we will still add this information to the information collection currently approved under OMB control number 0938–0964. In addition, based on this data, we do not expect any future impact to the Medicare Trust Fund.

We are further proposing in § 423.44(d)(9)(ii) that the Part D plan must provide a written notice of disenrollment to the member to advise them of the plan's intent to disenroll, as required under § 423.44(c) of this subpart. Lastly, we are proposing in § 423.44(d)(9)(iii) that the Part D plan must report to CMS any disenrollment based on fraud or abuse by the member. All information impacts related to providing a written notice to the member and notifying CMS of the disenrollment have already been accounted for under OMB control numbers 0938–0964 (CMS–10141).

N. SPAP or Other Payer Exception for Disenrollment for Failure To Pay (§ 423.44)

Section 1851(g)(3)(B)(i) of the Act allows MA plans to disenroll members who fail to pay premiums on a timely basis. Section 1860D–1(b)(1)(B)(v) of the Act directs us to adopt Part D disenrollment rules similar to the MA provisions in section 1851(g) of the Act. Additionally, section 1860D–1(b)(3)(A)(iii) of the Act states that disenrollment in a plan for failure to pay premiums will be considered a voluntary disenrollment action. In Part D implementing regulations (70 FR 4525), we established the basis for an optional involuntary disenrollment for failure to pay premiums as well as the disenrollment process. The basis for disenrollment for failure to pay premiums was established at § 423.44(b)(1)(i). The disenrollment process for failure to pay premiums was established at § 423.44(d)(1). In 2009, we added an exception to this disenrollment provision which prohibited plans from disenrolling individuals who are in premium withhold status (74 FR 1543). The premium withhold status exception was established at § 423.44(d)(1)(iv) and later renumbered to paragraph (v) in 2010 when we added the grace period requirement at § 423.44(d)(1)(iii) (75 FR 19816).

Section 1860D–23 of the Act directed the Secretary to establish coordination rules between State Pharmaceutical Assistance Programs (SPAPs) and Part D plan sponsors regarding the payment of premiums for Part D eligible individuals. SPAPs, and other third-party payer assistance programs, have the option to cover Part D premiums for individuals. Implementing regulation (70 FR 4525) established the requirement that Part D plan sponsors must permit SPAPs, and other entities, to coordinate benefits with the plan, including paying for premiums, at § 423.464(a).

To protect beneficiaries who have SPAPs, or other payers, cover their premiums, we propose to codify current policy that excepts certain prescription drug plan (PDP) members from being disenrolled for failure to pay plan premiums, at § 423.44(d)(1)(v). This policy is currently set out in sub-regulatory guidance, specifically section 50.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, that Part D plan sponsors have previously implemented and are currently following. We propose, at revised § 423.44(d)(1)(v), a disenrollment exception if the sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer. Sponsors would not be able to initiate the disenrollment process or disenroll members who qualify for this exception.

In addition, we are taking this opportunity to propose a technical correction to revise an erroneous cross reference in § 423.44(d)(1). Instead of referring to paragraph (d)(1)(iv), the language should refer to paragraph (d)(1)(v).

We are codifying longstanding guidance with these changes. All information impacts related to the involuntary disenrollment by the plan for failure to pay Part D plan premiums have already been accounted for under OMB control 0938–0964 (CMS–10141). Based on infrequent questions or complaints from Part D sponsors on these notices, we believe that these disenrollment requirements have been previously implemented and are currently being followed by sponsors. These updates do not add to the existing disenrollment process, so we do not believe there is any additional paperwork burden.

O. Possible End Dates for the SEP for Government Entity-Declared Disaster or Other Emergency (§§ 422.62 and 423.38)

Section 1851(e)(4)(D) of the Act authorizes the Secretary to establish MA special enrollment periods (SEP) for

Medicare-eligible individuals to elect a plan or change the individual's plan election when the individual meets an exceptional condition, as determined by the Secretary. Section 1860D–1(b)(3)(C) of the Act authorizes the Secretary to establish SEPs for exceptional circumstances for Medicare-eligible individuals to make Part D elections.

The SEPs for exceptional circumstances were historically included in our sub-regulatory guidance rather than in regulation. In 2020, we codified and amended a number of SEPs that had been adopted and implemented through sub-regulatory guidance as exceptional circumstances SEPs, including the SEP for Government Entity-Declared Disaster or Other Emergency (85 FR 33901, 33909). This SEP, as codified at § 422.62(b)(18) for enrollment in an MA or MA–PD plan and § 423.38(c)(23) for enrollment in a Part D-only plan, allows individuals who are or have been affected by an emergency or major disaster declared by a Federal, State, or local government entity, and did not make an election during another period of eligibility as a result of the disaster/emergency, to make an MA and/or Part D enrollment or disenrollment action. Although CMS originally proposed that this SEP would only apply to FEMA-declared disasters or emergencies, as finalized in 2020, the regulations also include State and local emergency or major disaster declarations (85 FR 33868). This SEP begins the date the disaster/emergency declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. This SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later.

In order to clarify the length of this SEP, we are proposing to revise the end date(s) for the SEP for Government Entity-Declared Disaster or Other Emergency. We are proposing two changes in §§ 422.62(b)(18) and 423.38(c)(23) regarding this SEP.

First, we are proposing that for State or local emergencies/disasters, the end date for the SEP may also be based on an emergency/disaster order automatically expiring pursuant to a State or local law, if such a law exists. Applicable State or local law could be statutes, regulations, local or municipal ordinance or code regarding the automatic expiration date of State or local emergency orders. If the announced incident period end date is different than the expiration date specified in State or local law, the announced incident end date controls the SEP end date. Under this proposal, the SEP ends based on the end of the emergency/disaster period, regardless of whether that period ends based on an announcement by the applicable authority or expires based on applicable State or local law.

Second, we are proposing an automatic incident end date which will apply if no end date for the period of disaster/emergency is otherwise identified within 1 year of the start of the SEP. This automatic incident end date will fall 1 year after the SEP start date, meaning that if no end date is otherwise identified, the SEP will be 14 full calendar months in length. For example, under our proposed changes, if no incident end date was identified in the declaration, or announced later, and there is no applicable expiration date provided by State or local law, CMS would consider the incident end date to be 1 year after the SEP start date and the SEP would end 2 full calendar months after that incident end date, which would result in a 14-month maximum SEP. We are seeking public comment on this automatic 1-year incident end date to determine if the 14-month maximum eligibility period for this SEP is sufficient. We propose that if the emergency/disaster declaration is extended, then the automatic 1-year incident end date would be from the date of the extension. This would address situations where a declaration of emergency or major disaster is renewed or extended (perhaps multiple times) so that the state of emergency or major disaster lasts for a year or more. These proposed changes will provide clear end dates for this SEP and should allow stakeholders to more easily calculate SEP length and determine beneficiary eligibility for the SEP.

Because an individual may elect a Medicare Advantage or Part D plan only during an election period, Medicare Advantage organizations and Part D sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible. Our proposal would not add to existing enrollment processes, so we believe any burden associated with this aspect of enrollment processing would remain unchanged from the current practice, and would not impose any new requirements or burden. All information impacts of this provision have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267), 0938–1378 (CMS–10718), and 0938–0964 (CMS–10141). In addition, Medicare Advantage organizations and Part D sponsors have previously implemented and are currently following the process to determine applicant eligibility for this SEP. We believe that changing the possible end date for this SEP will make a negligible impact, if any. We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

P. Updating MA and Part D SEPs for Changes in Residence and Codifying Procedures for Developing Addresses for Members Whose Mail Is Returned as Undeliverable (§§ 422.62, 422.74, 423.38 and 423.44)

Section 1851(b)(1)(A) of the Act provides that an individual is eligible to elect a Medicare+Choice (M+C), later known as Medicare Advantage (MA), plan only if the plan serves the geographic area in which the individual resides. Section 1851(b)(1)(B) of the Act provides for a continuation of enrollment option under which an MA organization offering an MA local plan may offer its enrollees the option to continue enrollment in the plan when they move out of the plan service area and into a continuation area, so long as the organization provides or arranges for coverage of all Medicare-covered benefits. In the June 1998 IFC, we adopted regulations to address the residency and continuation area requirements, at §§ 422.50(a)(3) and 422.54, respectively, as well as a regulation, at § 422.74(b)(2)(i), requiring that an MA organization must disenroll an individual who no longer resides in the plan service area.

Section 1860D–1(b)(1)(B)(i) of the Act generally directs CMS to use rules related to enrollment, disenrollment, and termination for Part D sponsors that are similar to those established for MA organizations under section 1851(b)(1)(A) of the Act. In addition, section 1860D–1(b)(3) of the Act provides CMS additional SEP authority, including the authority at 1860D–1(b)(3)(C) for the Secretary to establish special enrollment periods ''[i]n the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.''

In January 2005, we published a final rule (70 FR 4194) to establish at § 423.30(a) that an individual must reside in a Part D plan service area in order to be eligible to enroll in the plan and at § 423.44(b)(2) that a Part D plan sponsor is required to disenroll an

individual who no longer resides in the plan service area.

Section 1851(e)(4)(B) of the Act establishes that an individual who is no longer eligible to elect an MA plan because of a change in the individual's place of residence is eligible for a special election period (SEP) during which the individual may disenroll from the current plan or elect another plan. In the June 1998 interim final rule with comment period (63 FR 35073), we established at § 422.62(b)(2) an SEP for an individual who is not eligible to remain enrolled in an MA plan because of a change in his or her place of residence to a location out of the service area or continuation area. Likewise, in the January 2005 Part D final rule (70 FR 4194), we established at § 423.38(c)(7) an SEP for an individual who is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) where the PDP is offered are eligible for an SEP.

Current sub-regulatory guidance for these SEPs that are codified at §§ 422.62(b)(2) and 423.38(c)(7), as reflected in section 30.4.1 of Chapter 2 of the Medicare Managed Care Manual for MA and in section 30.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, provide that these SEPs are available not only to individuals who become ineligible for their current plan due to a move out of the service area of their current plan, but also to those who move within the service area of their current plan and have new plan options available to them, as well as to those who are not currently enrolled in a Medicare health or drug plan who move and have new plan options available to them. We propose to address the wider scope of these SEPs, as they are currently set out in sub-regulatory guidance, by amending §§ 422.62(b)(2) and 423.38(c)(7) to include individuals who move within the service area of their current plan and have new Medicare health or drug plan options available to them, as well as to those who are not currently enrolled in a Medicare health or drug plan who move and have new plan options available to them.

The intent of our proposal is to codify current policy as reflected in CMS's existing subregulatory guidance and that is being carried out currently by MA organizations and Part D plan sponsors. Codifying our current policy for these SEPs will provide transparency and stability for stakeholders about the MA and Part D programs and about the nature and scope of these SEPs.

Separate from, but related to, the aforementioned policy for disenrolling individuals who report that they no longer reside in the plan service area are the current regulations at § 422.74(d)(4)(ii) that require that MA organizations disenroll individuals who are absent from the service area for more than six months. However, § 422.74(d)(4)(iii) provides an exception for individuals enrolled in MA plans that offer a visitor/traveler benefit are permitted an absence from the service area for up to 12 months; such individuals are disenrolled if their absence from the service area exceeds 12 months (or the length of the visitor/traveler program if less than 12 months). As outlined at § 423.44(d)(5)(ii), PDP sponsors must disenroll PDP enrollees who are absent from the plan service area for more than 12 months.

In the event that member materials are returned to plan sponsors as undeliverable and a forwarding address is not specified, current sub-regulatory guidance directs the plan sponsor to document the return, retain the returned material and continue to send future correspondence to that same address, as a forwarding address may become available at a later date. See § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for Part D. In sub-regulatory guidance, we state that plan sponsors are to consider returned mail as an indication of a possible change in residence that warrants further investigation. As such, we encourage the plan sponsor to attempt to locate the member using any available resources, including CMS systems, to identify new address information for the member. We describe how plans should attempt to research a member's change of address at § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for Part D. Plan sponsors that are unable to contact the member or obtain current address information will disenroll the member upon expiration of the 6- or 12-month period of permitted temporary absence from the plan service area, as previously discussed.

Current MA guidance in § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual regarding research of potential changes in address is consistent with the MA regulation at § 422.74(d)(4)(i) providing that ''the MA organization must disenroll an individual if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved.'' The analogous Part D regulation at § 423.44(d)(5)(i) requires that the ''PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area,'' but the Part D regulation does not provide a basis similar to the MA regulation for when PDPs may start the process of researching and acting on a change of address that the plan learns about from a source other than the member. Although current Part D guidance in § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual allows PDPs to use information they receive from sources other than the member, specifically from either CMS or the USPS, as an indicator that a beneficiary may no longer reside in the service area, this is not codified in the Part D regulation. Therefore, we propose to align the Part D regulation with MA regulation by amending § 423.44(d)(5)(i) to state that a PDP must disenroll an individual if the PDP establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved out of the PDP service area.

Current sub-regulatory guidance does not identify returned mail as a basis for involuntary disenrollment. Materials plans send to members that include protected health information (PHI) and/or personal identifying information (PII), as well as materials intended to inform members of plan-specific information, such as premiums, benefits, cost-sharing, network and network changes and plan rules, have the potential for greater adverse impact on individual members, if returned as undeliverable, than materials such as newsletters, flyers and other items covering general health and wellness. To provide additional clarity to plan sponsors in their efforts to ascertain the residency status of members when there is an indication of a possible temporary or permanent absence from the service area, we are proposing to amend § 422.74 by adding paragraphs (d)(4)(ii)(A) and (d)(4)(iii)(F) for MA and to amend § 423.44 by revising paragraph (d)(5)(ii) for Part D to state that an individual is considered to be temporarily absent from the plan service area when any one or more of the required materials and content referenced in §§ 422.2267(e) and 423.2267(e), if provided by mail, is returned to the plan sponsor by the US Postal Service as undeliverable and a forwarding address is not provided. Codifying current sub-regulatory guidance regarding the use of returned mail as a basis for considering a member potentially out of area would provide a

regulatory basis for plan sponsors to apply the 6- and 12-month timeframes as previously described, as well as the current practice of disenrolling individuals when the plan sponsor is unable to communicate with them using the residence address provided by the individual to the plan sponsor. Since plan sponsors are required by regulation to continue to mail certain materials to enrollees until the point at which the individual is no longer enrolled in the plan, we believe that it is important to codify the basis on which plan sponsors are to consider an individual to be temporarily out of the plan service area and able to be disenrolled, after an appropriate period of time, thus bringing about the cessation of any additional member material mailings.

Codifying our current policy for temporary absences from the plan service area, the sources of information on which plan sponsors may make related eligibility determinations, and the implications for disenrollment will provide transparency and stability for stakeholders about the MA and Part D programs and about plan service area requirements for the MA and Part D programs.

These proposals are a codification of longstanding MA and Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. Because an individual may elect an MA or Part D plan only during an election period and may continue enrollment in an MA or Part D plan only if the individual resides in the plan service area, or for some MA plans, the plan continuation area, MA organizations and Part D plan sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible and to determine the point at which an enrollee is no longer eligible for the plan and must be disenrolled. Our proposal would not add to existing enrollment and disenrollment processes, so we believe any burden associated with these aspects of enrollment and disenrollment processing would remain unchanged from the current practices, and would not impose any new requirements or burden. All information impacts related to the determination of eligibility for an election period and to the disenrollment of individuals who become ineligible for an MA or Part D plan based on the residency requirements have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

Q. Codify the Term ''Whole Calendar Months'' (§§ 422.74 and 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that an MA organization may involuntarily terminate an individual's election in a MA plan if monthly basic and supplemental beneficiary premiums are not paid timely, and provides for a grace period for payment of such premiums. Consistent with this section of the Act, the Part C regulations set forth our requirements with respect to optional involuntary disenrollment procedures under § 422.74.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) enacted the Medicare Advantage (MA) program, which replaced the M+C program established under title XVIII of the Act, and amended title XVIII of the Act to add a new Part D (Voluntary Prescription Drug Benefit Program). Section 1860D–1(b)(1)(B)(v) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall use rules similar to (and coordinated with) the rules for an MA plan established under section 1851(g) (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section) of the Act. Consistent with these sections of the Act, the Part D regulations set forth our requirements with respect to optional involuntary disenrollment procedures under § 423.44.

In 2010, CMS amended the Part C and Part D regulations regarding optional involuntary disenrollment for nonpayment of premiums to require a minimum grace period of 2 months before any disenrollment occurs. This timeframe was established to provide adequate time for organizations to respond to instances in which individuals fail to pay their premiums, and for affected enrollees to take steps to remedy the situation and avoid disenrollment. These requirements were codified at § 422.74(d)(1)(i)(B)(1) (75 FR 19804) and § 423.44(d)(1)(iii)(A) (75 FR 19816). CMS also revised these regulations to include the requirement that the grace period begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later. These regulations were codified at § 422.74(d)(1)(i)(B)(2) (75 FR 19804) and § 423.44(d)(1)(iii)(B) (75 FR 19816).

In subsequent subregulatory guidance in section 50.3.1, Chapter 2 of the Medicare Managed Care Manual and section 50.3.1, Chapter 3 of the Medicare Prescription Drug Benefit Manual we defined the grace period for nonpayment of plan premium as a *whole* number of calendar months, not fractions of months. As the term ''whole calendar months'' is not specifically mentioned in the Part C and Part D regulations, we are proposing to revise §§ 422.74(d)(1)(i)(B)(1) and 423.44(d)(1)(iii)(A) to include the requirement that the grace period be at least 2 whole calendar months, to begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later. To illustrate this proposal, we provide the following example.

An MA or Part D plan has a 2-month grace period for premium payment. The grace period cannot begin until the individual has been notified of (billed for) the actual premium amount due, with such notice/bill specifying the due date for that amount and providing an opportunity to pay. On January 10th, a member is billed for his or her premium which is due on February 1. The member does not pay this premium and on February 7th, the sponsor sends the notice required by § 422.74(d)(1)(ii) or § 423.44(d)(1)(ii). The member does not act in response to this notice or any subsequent premium bills and payments are not made for February or March. The grace period is the months of February and March. If the member does not pay the unpaid plan premiums before the end of March, the individual would be disenrolled as of April 1.

Codifying this policy that a plan must provide a grace period of at least 2 whole calendar months will provide transparency and stability for stakeholders, and align with longstanding sub-regulatory guidance described in section 50.3.1, Chapter 2 of the Medicare Managed Care Manual and section 50.3.1, Chapter 3 of the Medicare Prescription Drug Benefit Manual regarding timeframes for disenrollment, which establish that the grace period must be a whole number of calendar months and cannot include fractions of months.

Plan sponsors that have chosen to disenroll individuals based on unpaid premiums already have procedures in place to implement a grace period that is a minimum of 2 months in length. Based on infrequent complaints or questions from sponsors, we believe that plan sponsors are complying with this guidance, and we are not proposing any

changes to the requirements or process for involuntary disenrollment that plan sponsors have previously implemented and are currently following. All burden impacts of these provisions have already been accounted for under OMB control number 0938–0753 (CMS–R–267) for Part C and OMB control number 0938–0964 (CMS–10141). There is also no impact to the Medicare Trust Fund.

R. Researching and Acting on a Change of Address (§§ 422.74 and 423.44)

As discussed in our proposal for Developing Addresses for Members Whose Mail is Returned as Undeliverable and SEP for Changes in Residence (§§ 422.62, 422.74, 423.38, 423.44), section 1851(b)(1)(A) of the Act provides that an individual is eligible to elect an MA plan only if the plan serves the geographic area in which the individual resides, and section 1860D–1(b)(1)(B) of the Act generally directs CMS to use rules related to enrollment, disenrollment, and termination for Part D sponsors that are similar to those established for MA organizations under section 1851(b)(1)(A) of the Act.

Pursuant to regulations at § 422.74(c) for MA and § 423.44(c) for Part D, MA organizations and Part D plan sponsors are currently required to issue a disenrollment notice when an enrollee is disenrolled for not residing in the plan service area. Existing sub-regulatory guidance includes a requirement that MA organizations and Part D plan sponsors issue the disenrollment notice within 10 days of the plan learning of the permanent move. See § 50.2.1.5 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.6 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, respectively. In the case of MA plan enrollees who are disenrolled because they are absent from the service area for more than six months, the disenrollment notice must be provided within the first ten calendar days of the sixth month. Individuals enrolled in MA plans that offer a visitor/traveler benefit are permitted an absence from the service area for up to 12 months; such individuals are disenrolled if their absence from the service area exceeds 12 months (or the length of the visitor/traveler program if less than 12 months). In this scenario, the MA organization must provide notification of the upcoming disenrollment to the enrollee during the first ten calendar days of the 12th month (or the last month of the allowable absence, per the visitor/traveler program). PDP enrollees are disenrolled if they are absent from the plan service area for more than 12 months. For these cases, the disenrollment notice must be provided within the first 10 calendar days of the 12th month. For instances in which a plan learns of an individual's absence from the service area after the expiration of the period of time allowed under the applicable regulation, the plan would provide the disenrollment notice within 10 calendar days of learning of the absence.

Although we have previously codified the requirement to issue a disenrollment notice when an individual is disenrolled due to an extended absence from the plan service area, or a change in residence to a location outside the service area, the 10-day timeframe for issuing that notice is reflected only in sub-regulatory guidance. We propose to amend the MA and Part D plan disenrollment notification requirements to include the 10-day timeframe that is currently reflected in sub-regulatory guidance. Specifically, we are proposing to codify at § 422.74(d)(4)(iv) and at § 423.44(d)(5)(i) and (d)(5)(ii) a timeliness requirement of 10 calendar days for issuing notices for disenrollment's based on the residency requirements. Separate from the disenrollment notification requirements described in the preceding paragraphs is a documentation retention requirement currently reflected in § 50.2.1.3 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. It has been CMS policy that MA organizations and Part D plan sponsors document their efforts to determine whether an enrollee has relocated out of the plan service area or has been absent from the service for a period of time in excess of what is allowed; however, our expectation that plans document their research efforts, although outlined in sub-regulatory guidance, is not codified. As such, we propose to amend the MA and Part D regulations to include the requirement that plans document their efforts to determine an enrollee's residency status.

We are proposing to codify at § 422.74(d)(4)(i) and at § 423.44(d)(5)(i) and (d)(5)(ii) that MA organizations and Part D plan sponsors must document the basis for involuntary disenrollment actions that are based on the residency requirements.

The intent of our proposal is to codify current disenrollment notice policy, as reflected in § 50.2.1.5 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.6 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, and also codify the current documentation policy that is currently reflected in § 50.2.1.3 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, all of which are policies that are being carried out currently by MA organizations and Part D plan sponsors. Codifying our current policies regarding notification of disenrollment and document retention will provide transparency and stability for stakeholders about the MA and Part D programs and about the nature and scope of these notification and retention policies.

These proposals are a codification of longstanding MA and Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. MA organizations and Part D plan sponsors already have procedures in place to provide disenrollment notifications and to retain documentation related to such disenrollments. Our proposal would not add to existing processes, so any burden associated with this aspect of disenrollment processing and document retention would remain unchanged from current practices and would not impose any new requirements or burden. All information impacts related to these existing practices have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

S. Part D Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members (§§ 423.32 and 423.36)

Section 1860D–1(b) of the Act establishes the enrollment and disenrollment process for Part D eligible individuals in prescription drug plans. This section of the Act grants the Secretary the authority to establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. In January 2005, the Part D implementing regulations established the enrollment and disenrollment processes for Part D prescription drug plans. The enrollment and disenrollment processes for prescription drug plans are codified in regulation at §§ 423.32 and 423.36, respectively (70 FR 4525).

Section 1860D–1(b)(1)(B) of the Act directs the Secretary to adopt Part D enrollment rules ''similar to'' and coordinated with those under Part C. In 1998, Part C implementing regulations (and subsequent correcting regulations) added the requirement that allowed an exception for employer/union group health plan (EGHP) sponsors to process election forms for Medicare-entitled group members (63 FR 52612, 63 FR

35071). These requirements were codified in the Part C regulations but were not codified in the Part D regulations.

We are proposing to codify this existing policy to provide transparency and ensure consistency between the Part C and Part D programs. Specifically, we are proposing at new §§ 423.32(i) and 423.36(e) to permit a Part D plan sponsor that has a contract with an employer or union group to arrange for the employer or union to process enrollment and disenrollment elections for Medicare-entitled group members who wish to enroll in or disenroll from an employer or union sponsored Part D plan. As outlined in sections 60.5.1 and 60.5.2 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, retroactive enrollments and disenrollments are permitted for up to 90 days to conform to the payment adjustments described under §§ 422.308(f)(2) and 423.343(a). In addition, to obtain the retroactive effective date of the election, the individual must certify receipt of the group enrollment notice materials that include the summary of benefits offered under the PDP, as provided in sections 40.1.6 and 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. Once the enrollment or disenrollment election is received from the employer, the Part D plan sponsor must submit the disenrollment to CMS within the specified timeframes described in section 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Our intent is to align the Part D regulation with the requirements that MA organizations follow in existing Part C regulations at §§ 422.60(f) and 422.66(f) and codify existing policies in the sub-regulatory guidance in Chapter 3 of the Medicare Prescription Drug Benefit Manual. Under section 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, retroactive transactions may be necessary and are permitted if a delay exists between the time the individual completes the enrollment or disenrollment request through the employer's election process and when the request is received by the Part D plan sponsor. Further, we state in current sub-regulatory guidance at section 60.5.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual that the option to submit limited EGHP retroactive enrollment and disenrollment transactions is to be used only for the purpose of submitting a retroactive enrollment into an EGHP made necessary due to the employer's delay in forwarding the completed enrollment request to the Part D plan sponsor.

This proposal is a codification of existing Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. Based on infrequent complaints and questions from plans and beneficiaries related to current policies, which have been previously implemented and are currently being followed by plans, we conclude that there is no additional paperwork burden. All information impacts related to this provision have already been accounted for under OMB control numbers 0938–1378 (CMS–10718) for Part D enrollment requests and 0938–0964 (CMS–10141) for Part D disenrollment requests.

T. Single-Tier Benefit Requirement for Defined Standard Coverage (§§ 423.100, 423.120, 423.2267)

We propose to codify our longstanding subregulatory policy, as described in the Final Coverage Year (CY) 2015 Part D Call Letter (hereinafter referred to as the ''Final CY 2015 Part D Call Letter,'' and available at *https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2015.pdf*), that a plan offering Defined Standard coverage apply a single-tier benefit structure to drugs on its formulary (if it uses a formulary, as defined at § 423.4). In addition, we propose to codify our longstanding subregulatory policy that all communications and marketing materials (as these terms are defined at § 423.2260) for a plan offering Defined Standard coverage must reflect a single-tier benefit structure.

Under sections 1854(a)(1)(A) and 1860D–11(b) of the Act, initial bid submissions for all MA plans, MA–PD plans, and PDPs must be in a form and manner specified by the Secretary. To facilitate Part D sponsors' submission of their bids, we provided guidance regarding Incomplete and Inaccurate Bid Submissions on page 163 of the Final CY 2020 Part D Call Letter (hereinafter referred to as the ''Final CY 2020 Part D Call Letter,'' and available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf*) that a formulary crosswalk is one of the constituent components of a complete bid submission for a Part D sponsor that is offering a Part D plan with a formulary. Additionally, in the February 3, 2022 HPMS memo titled, ''Contract Year (CY) 2023 Final Part D Bidding Instructions'' (available at *https://www.cms.gov/files/document/2023partdbiddinginstructions.pdf*), we referenced the Final CY 2020 Part D Call Letter policy on Incomplete and Inaccurate Bid Submissions as applicable for CY 2023. Further, the Bid Submission User Manual for Contract Year 2023, Chapter 10, Bid Submission Pre-Upload Requirements and Uploads (hereinafter referred to as ''Chapter 10'' and available in the HPMS via the following path: Plan Bids/Bid Submission/CY 2023/View Documentation/Bid Submission User Manual/Chapter 10), provides detailed information about the formulary crosswalk.

Chapter 10 instructs all contracts that submitted a formulary through HPMS to submit a formulary crosswalk. Additionally, in order for the Formulary Crosswalk to be considered complete, Part D sponsors are also instructed to: (1) assign a formulary to all plans that offer Part D and are a part of the contract that submitted the formulary; and (2) assign all formularies submitted for an organization to at least one plan. Further, Chapter 10 provides that one formulary may be mapped to one or more plans. The ability for plans to assign a given formulary to multiple plans reduces Part D sponsor and CMS administrative burden by reducing the number of formularies that CMS must review and Part D sponsors must maintain.

Since the beginning of the Part D program, we have interpreted section 1860D–2(b) of the Act to provide two distinct types of standard prescription drug coverage—''Defined Standard coverage'' and ''actuarially equivalent standard coverage.'' Section 1860D–2(b)(2)(A)(ii) of the Act provides that Part D sponsors offering actuarially equivalent standard coverage will be permitted to substitute cost-sharing requirements (including multi-tier benefit structures tied to Part D plan formularies and particular pharmacies in a Part D plan's network) for costs above the annual deductible and up to the catastrophic coverage limit, provided that those alternative cost-sharing requirements are actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to catastrophic coverage. Also, since the beginning of the Part D program, we have interpreted this provision to permit multi-tier benefit structures for actuarially equivalent standard coverage but not for Defined Standard coverage (70 FR 4237).

As is noted on page 55 of the Final CY 2015 Part D Call Letter, for a plan using a formulary (as defined at § 423.4), we expect that the formulary structure submitted for a plan offering Defined

Standard coverage will be consistent with a plan benefit package (PBP) submission that does not include a multi-tier benefit structure. Similarly, we have stated in our Formulary Submission Module and Reports Technical Manual (available at *https://www.cms.gov/files/document/cy2022formularyplanmanual5.pdf*) that formularies that will only be associated with plans offering Defined Standard coverage must be submitted as having a single-tier benefit structure. We made an exception to this policy such that if a plan offering Defined Standard coverage uses a formulary that is linked (via the Formulary Crosswalk) to at least one other plan with a multi-tier benefit structure (that is, a plan offering Actuarial Equivalent Standard, Basic Alternative, or Enhanced Alternative coverage). In other words, a given formulary (as defined in *§ 423.4*) applies to all plans to which such formulary has been assigned, but any submitted multi-tier benefit structures are plan-specific and only apply to the individual plans that offer coverage other than Defined Standard.

The Final CY 2015 Part D Call Letter also instructed that all marketing materials for plans offering Defined Standard coverage reflect a single-tier benefit structure regardless of whether such plan offering Defined Standard coverage uses a formulary that is associated with other plans that offer multi-tier benefit structures.

Because we continue to receive questions from Part D sponsors about our policy that a plan offering Defined Standard coverage have a single-tier benefit structure, we are taking this opportunity to clarify a common point of confusion by proposing to codify this longstanding subregulatory policy, as summarized below. Additionally, with regard to the formulary crosswalk policy, we have previously used the terms ''associated,'' ''mapped,'' ''linked,'' and ''assigned'' synonymously, but in order to minimize confusion, we have chosen to use the term ''assign'' in our proposed regulatory requirements.

First, we propose to define the term ''formulary crosswalk'' at § 423.100 as the process during bid submission by which a formulary (as defined at § 423.4) is assigned to one or more Part D plans with single- or multi-tier benefit structures.

Second, we propose to add new paragraph § 423.120(b)(9) to codify that a Part D plan offering Defined Standard coverage may not apply multi-tier benefit structures to the formulary (as defined at § 423.4) to which it has been assigned via the formulary crosswalk (as defined at § 423.100) as part of the bid submission process. We also propose to codify an exception in the case that such formulary has also been assigned to one or more other Part D plans that use multi-tier benefit structures such that the multi-tier benefit structures used by the other Part D plans offering coverage other than Defined Standard coverage would not apply to the plan offering Defined Standard coverage.

Finally, because various required marketing and communications materials, including (but not limited to) the formulary document, have been redesignated as communications materials, as defined at § 423.2260, we propose to codify our subregulatory policy that a plan offering Defined Standard coverage display a single-tier benefit structure in all relevant marketing and communications materials. Specifically, at new § 423.2267(e)(42), we propose to require that, when discussing the Part D plan's formulary, a plan offering Defined Standard coverage convey that all covered drugs have a single-tier benefit structure. This would be model content included in all relevant communications and marketing materials (as defined at § 423.2260) that pertain to the formulary or preferential status of the covered Part D drugs—including the complete and abridged formulary, Summary of Benefits, Evidence of Coverage, and other materials, as applicable.

We have been monitoring compliance with this policy via our annual formulary review and approval process, consistent with the requirements at § 423.120(b). Since this review is already being performed and plans are already in compliance, there is no additional paperwork burden associated with codifying this longstanding subregulatory policy.

We solicit comment on these proposals.

U. Shortages of Formulary Drug Products During a Plan Year (§ 423.120)

Drug shortages and their impact on the healthcare system have been a concern for decades. FDA reports that drug shortages peaked in 2011 with 251 new shortages, but have since declined to 43 in 2020.[160] Despite this progress, drug shortages received renewed attention as a result of supply chain disruptions during the Coronavirus Disease 2019 (COVID–19) pandemic. As part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, Congress commissioned the National Academies of Sciences, Engineering, and Medicine to examine and report on vulnerabilities in the U.S. medical supply chain.[161] While other government agencies pursue strategies to track and mitigate drug shortages, in this proposed rule, we propose to codify existing subregulatory guidance, first released in the July 21, 2009 Health Plan Management System (HPMS) memorandum titled ''Shortages of Formulary Drug Products During a Plan Year'' [162] and subsequently incorporated into chapter 5 of the Prescription Drug Benefit Manual,[163] describing expectations of Part D sponsors when shortages impact drugs on their Part D plan formulary. We also propose to broaden the scope of requirements beyond current guidance to reflect the availability of interchangeable biological products.

Section 1860D–11(e)(2)(D)(i) of the Act requires CMS to approve Part D plans only if CMS does not find that the design of the plan and its benefits, including any formulary, are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. Accordingly, CMS' annual formulary review and approval process includes extensive checks to ensure adequate representation of all necessary Part D drug categories or classes for the Medicare population. These checks have been previously described in CMS' January 10, 2014 proposed rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 2019). Such formulary requirements are a beneficiary protection counterbalancing CMS' statutory prohibition against requiring a particular formulary or interfering with negotiations between Part D sponsors, manufacturers, and pharmacies, consistent with section 1860D–11(i) of the Act. Because Part D drug shortages have the potential to undermine the formulary approval process and interrupt beneficiary therapy, CMS is proposing to codify requirements for Part D sponsors relating to formulary drug shortages to mitigate potential disruption.

[160] U.S. Food and Drug Administration. Eighth Annual Report on Drug Shortages for Calendar Year 2020. Available from: *https://www.fda.gov/media/150409/download.*

[161] National Academies of Sciences, Engineering, and Medicine. 2022. Building Resilience into the Nation's Medical Product Supply Chains. Washington, DC: The National Academies Press. *https://doi.org/10.17226/26420.*

[162] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/HPMS-Guidance-History-Items/CMS1224655.*

[163] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.*

Existing guidance names FDA as the definitive source of drug shortage information. We are therefore proposing to add a new paragraph (g) to § 423.120 to specify that our proposed drug shortage requirements would apply in the case of shortages listed on the FDA website at *https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages* and corresponding database at *https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.* If a shortage becomes market withdrawal and therefore the product is no longer listed on the FDA drug shortage website, then the proposed requirements would no longer apply.

In order to minimize unnecessary changes in therapy resulting from temporary shortages of multiple-source formulary drug and biological products, we propose at new paragraph § 423.120(g)(1) to require Part D sponsors to permit enrollees affected by a shortage to obtain coverage for a therapeutically equivalent drug or an interchangeable biological product, if any, for at least the duration of the shortage. As proposed at § 423.120(g)(1)(i), Part D sponsors would be required to permit enrollees affected by a shortage to obtain coverage for a therapeutically equivalent or interchangeable non-formulary alternative without requiring those enrollees to meet formulary exception requirements at § 423.578(b). In the case where a therapeutically equivalent or interchangeable alternative is on the formulary but requires prior authorization or step therapy, as proposed at § 423.120(g)(1)(ii), Part D sponsors would be required to permit enrollees affected by a shortage to obtain coverage for the formulary alternative without requiring those enrollees to satisfy prior authorization or step therapy requirements.

When applicable, Part D sponsors should allow pharmacies to utilize a value of ''8'' (Substitution Allowed—Generic Drug Not Available in Marketplace) in field 408–D8 (Dispense as Written/Product Selection Code) of the National Council for Prescription Drug Programs (NCPDP) version D.0 Telecommunication standard (or the applicable value and version at the time) to specify that an equivalent brand product is being dispensed due to the unavailability of any generic formulary products. Nothing in this proposal supersedes State pharmacy laws, which determine a pharmacist's authority to automatically substitute therapeutically equivalent drugs or interchangeable biological products for the reference product, or vice versa. A new prescription for the alternative product may be required.

We are also proposing, at new paragraph (g)(2), to specify that the Part D sponsor would not be required to charge the cost sharing that applies to the unavailable formulary product for the alternative product and may charge the applicable sharing that would apply to the alternative therapeutically equivalent or interchangeable product's formulary status and the plan benefit design. That is, if the alternative product is on the formulary, the enrollee would be expected to pay the cost sharing that would normally apply based on the plan benefit design and if the alternative product is non-formulary, then the enrollee would be expected to pay the cost sharing associated with formulary exceptions. This policy would not preclude an enrollee affected by a shortage from seeking a formulary exception consistent with § 423.578(b) to obtain access to a non-formulary product or to a formulary product requiring prior authorization or step therapy beyond the duration of the shortage; nor would this policy preclude enrollees affected by a shortage from seeking a tiering exception, consistent with § 423.578(a), to obtain access to the alternative formulary product at a more favorable cost sharing.

Under the current proposal, Part D sponsors would be required to cover a therapeutically equivalent drug or interchangeable biological product as an alternative to the formulary product subject to shortage if there is claim submitted for the alternative. However, Part D sponsors may work with enrollees and providers to determine appropriate alternative drugs since suitable options may vary based on clinical needs, costs, or other factors. For example, if a generic formulary drug is unavailable but the therapeutically equivalent brand name product is available and on the formulary, an enrollee may prefer to switch to an alternative generic product rather than pay the associated brand cost sharing or pursue a tiering exception for the brand product.

The requirements we are proposing at § 423.120(g) would not require changes to the Part D sponsor's formulary; rather, they would require, for the duration of a shortage, coverage of alternative therapeutically equivalent products in lieu of the product in shortage. If a Part D sponsor decides to remove a product from its formulary due to long-term shortage or if the shortage becomes a market withdrawal, the requirements currently codified at § 423.120(b)(5), which we are proposing to revise as discussed in section III.Q. of this proposed rule, would apply.

We solicit comment on this proposal.

V. Validity of DEA Registration Numbers for Controlled Substances (§ 423.120(c))

In this section, we propose to amend § 423.120(c) to codify in regulation our current policy that Part D sponsors must confirm the validity of a prescriber's Drug Enforcement Administration (DEA) registration number for a controlled substance, if the number is on the drug claim. Or, if the prescriber's DEA registration number is not on the Part D claim, the sponsor must use prescriber identifier data sources to cross-reference the prescriber's individual National Provider Identifier (NPI) number, which is required on all Part D drug claims,[164] to the prescriber's DEA registration number for validation. Under § 423.104(h), a Part D sponsor may provide benefits only for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription. A ''valid prescription'' is defined in § 423.100 as a prescription that complies with all applicable State law requirements constituting a valid prescription.

Prescriptions are regulated under State laws which may incorporate Federal law and regulations. An example of such incorporation is the Drug Control Act of Virginia, Va. Code § 54.1–3408.01A, ''Requirement for Prescriptions,'' which states that a prescription for a controlled substance other than one controlled in Schedule VI ''shall also contain the Federal controlled substances registration number assigned to the prescriber.'' [165]

While compliance with applicable Federal and State laws related to dispensing of prescription drugs is primarily the responsibility of pharmacists, since plan year 2012, CMS has had a policy on DEA registration numbers in the Part D Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections, Section 90.2.4 ''Controlled Substances'' (hereinafter referred to as ''Manual Chapter 5''). The purpose of this policy is to support, as feasible, these frontline pharmacists' efforts to comply with State and DEA requirements with respect to controlled substances. We propose to codify this policy by requiring that Part D sponsors confirm the validity of DEA registration numbers on Schedule II–V drug claims or, if the prescriber's DEA registration

[164] 42 CFR 423.120(c)(5)(i).

[165] DEA regulations also address requirements regarding prescriptions for a controlled substance. See 21 CFR 1306.

number is not on the Part D claim, the sponsor must use prescriber identifier data sources to cross-reference the prescriber's Type 1 NPIs on these claims to the prescriber's DEA registration number for validation. In addition, we propose that sponsors be required to confirm that the controlled substance prescribed is consistent with the prescriber's DEA Schedule registration.

Type 1 NPIs are obtained by individual health care providers. (With respect to Part D claims, we refer to them in this section as ''prescriber NPIs''). Type 2 NPIs are obtained by organization health care providers and organizational health care providers are discussed further below.[166]

Section 90.2 of Manual Chapter 5 notes that sources of State and Federal data on providers, in addition to prescriber identifier validation services from commercial vendors, are available to support sponsor efforts at such validation. This means that sponsors can use public and private data when cross-referencing prescriber NPIs to DEA registration numbers, if the prescriber has a DEA registration number. It is our understanding that this is indeed what Part D sponsors and their pharmacy benefit managers (PBMs) currently do—that is, they use databases to cross-reference prescriber NPIs to DEA registration numbers when they receive a Part D claim for a controlled substance.

We further propose that if a Part D sponsor finds a valid and active DEA registration number for the prescriber of a controlled substance, and an associated schedule that is appropriate for the drug, then the sponsor must process the claim under the other coverage parameters of applicable Part D plan. If the sponsor finds a DEA registration number, but it is not valid or active, or the associated schedule for the drug is not appropriate, the sponsor must reject the claim and send the pharmacy an electronic code with the reason for the rejection.

We note that in rejecting the claim, the sponsor should not return the designated code to trigger the delivery of the standardized pharmacy notice to the enrollee, as the claim has been rejected because it does not contain all necessary data elements for adjudication. (See section 40.12.3 -Part D Coverage Determination Notices—in the Parts C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance).[167] With respect to written member requests for reimbursement, we propose that if the Part D sponsor determines that the DEA registration number of the prescriber was not valid or not active or there was not an associated schedule that was consistent with the drug for which the member requested reimbursement, then the Part D sponsor not only must deny the member request for reimbursement, but must also provide the beneficiary with a written notice explaining the coverage determination consistent with the notice requirements at § 423.568(g).

It is our understanding that some prescribers, such as hospital residents, prescribe controlled substances under an organizational health care provider's DEA registration number. We received reports in the past that sponsors were rejecting claims for controlled substances when a prescriber was prescribing under a hospital's or institution's DEA registration number, and the prescriber did not have an individual DEA registration number. We expressed concern at the time through guidance [168] that such rejections may interfere with beneficiary access to needed medications and result from a misinterpretation of our guidance. We also stated that we did not believe that sponsors have reasonable access to the information necessary to research the relationship of individual prescribers to hospitals' or institutions' DEA registration numbers for every claim, and we noted in our guidance that this is not expected. Therefore, consistent with our current guidance, we propose that if there is no individual prescriber DEA registration number found to validate, a Part D sponsor is not required to take any further action when processing a claim for a controlled substance in terms of validating a DEA registration number. In other words, we are proposing that the sponsor must check the validity of the DEA registration number only when there is an individual prescriber DEA registration number associated with the Type I NPI on the Part D claim.

Although this proposal would codify our current policy, we understand that at least some sponsors reject all claims for controlled substances for which they cannot validate the prescriber's DEA registration number and schedule. We speculate that these sponsors want to have an electronic record of the pharmacist using an override code to validate that the prescriber is lawfully prescribing controlled substances. We solicit comment on whether we should require sponsors to reject all claims for controlled substances for which they cannot validate the DEA registration number and schedule, and what impact this adjustment in policy would have on beneficiary access to controlled substances covered by Part D, if any.

We propose to codify our existing DEA registration number policy at § 423.120 by updating the header for paragraph (c) and by adding a new paragraph (7) as follows:

- The header of paragraph (c) would be changed to ''Use of standardized technology and identifiers.''
- New paragraph (c)(7)(i) would establish that a D sponsor must attempt to confirm the validity of a prescriber DEA registration number for a pharmacy claim for a Schedule II, III, IV or V drug, and that if the DEA registration number is not on the claim, the sponsor must cross-reference the prescriber's Type 1 NPI on the claim to any associated individual prescriber DEA number.
- New paragraphs (c)(7)(ii)(A) and (B) would specify that if the DEA registration number is not valid or active or the DEA registration number does not have an associated Schedule that is consistent with the drug for which a claim was submitted, the Part D sponsor must reject the claim and provide the pharmacy with the electronic reason code when rejecting the claim.
- New paragraph (7)(iii) would specify that if the pharmacy confirms the validity of the DEA registration number via electronic override code, or the sponsor is not able to cross-reference the Type 1 NPI to a prescriber DEA registration number, the sponsor must process the claim under the applicable benefit plan rules.
- New paragraph (c)(7)(iv) would specify that, with respect to written member requests for reimbursement, the Part D sponsor must determine whether the DEA registration number of the prescriber was valid and active for the date of service, and if the DEA registration number had an associated Schedule that was consistent with the drug for which the member request for reimbursement was submitted for the date of service. Consistent with proposed new paragraphs (7)(iv)(A) and (B), if the DEA number was not valid or active, or there was not an associated Schedule that was consistent with the drug, the Part D sponsor would be required to deny the member request for reimbursement and provide the

[166] MLN Booklet, ''NPI:What You Need to Know'' (March 2022), *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/NPI-What-You-Need-To-Know.pdf.*

[167] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

[168] ''HPMS Memo,'' Clarification of Chapter 5 of the Prescription Drug Benefit Manual, Section 90.2.4—Controlled Substances'' (May 21, 2013).

beneficiary with a written notice consistent with § 423.568(g).

As is the case with our current subregulatory policy, the purpose of our proposal is to ensure, to the extent feasible, that covered Part D drugs are dispensed upon valid prescriptions. We solicit comment on this proposal. Also, given the interactions we have had with Part D sponsors about our current controlled substances policy, we assume all sponsors are currently complying. Therefore, we conclude that there would be no additional paperwork burden for sponsors resulting from this proposal.

W. Codifying Current Part D Transition and Continuity of Care Policies (§§ 423.100 and § 423.120)

1. Overview and Summary

Under § 423.120(b)(3), Part D sponsors must provide certain enrollees a transition fill to avoid interruption in drug therapy when a drug is non-formulary, or on-formulary but subject to utilization management (UM) restrictions, so that the enrollee has time to switch to a therapeutic alternative drug or complete an exception request to maintain coverage of an existing drug based on medical necessity reasons. Thus, the purpose of providing a transition supply is to promote continuity of care and avoid interruptions in drug therapy.[169] Sponsors must also send enrollees a notice when they provide a transition fill.

The Part D transition requirement was first codified in our January 2005 Part D final rule (70 FR 4194) [170] under the authority of section 1860D–11(d)(2)(B) of the Act, which provides CMS with authority similar to that provided to the Director of the Office of Personnel Management with respect to health benefit plans to prescribe reasonable minimum standards for health benefits plans. We noted in that final rule that failure to appropriately transition certain beneficiaries could result in aggravation of certain medical conditions including, in some cases, hospitalization, which could ultimately increase costs to Medicare under Parts A and B (70 FR 4264).

Part D transition guidance is contained in Chapter 6 of the Medicare Prescription Drug Benefit Manual (Manual Chapter 6),[171] Section 30.4—Part D Drugs and Formulary Requirements. While most of the transition requirements are codified at § 423.120(b), there are some aspects of the current guidance in section 30.4 of Manual Chapter 6 that are not. Therefore, the purpose of this proposal is to codify those aspects of the current Part D transition guidance in regulation. In some cases, as detailed later in this section, our proposed regulation would clarify the policies reflected in current guidance.

Specifically, we propose to codify our policies with respect to the following topics: 1) quantity limits (QLs); 2) the minimum 108-day lookback period; 3) P&T committee role in transition; 4) transition notice timeframes; 5) level of care changes; and 6) (LTC) emergency supply.

2. Quantity Limits (QLs) During Transition

Currently, under § 423.120(b)(3), a sponsor is required to provide for an appropriate transition for an enrollee if the Part D drug is on the plan's formulary but requires prior authorization or step therapy. We propose to add to § 423.120(b)(3) that certain quantity limits (QLs) would require a sponsor to provide for an appropriate transition for an enrollee if the Part D drug is on the plan's formulary. This proposal, if finalized, would apply both for a current enrollee when a QL has been added to a drug on the plan's formulary that is lower than the beneficiary's current dose, and for a new enrollee when an existing QL for a formulary drug is lower than the beneficiary's current dose. This proposal is consistent with Section 30.4 of Manual Chapter 6.

We also propose an exception to the proposal that QLs would require a sponsor to provide for an appropriate transition for an enrollee if the Part D drug is on the plan's formulary. Specifically, we propose that QLs that are ''safety-based claim edits,'' meaning those claim edits that are consistent with drug utilization review (DUR) requirements described at § 423.153(c)(2) to prevent unsafe or inappropriate dosing, would continue to be applied to transition supplies. We believe it is necessary to continue to allow ''safety-based claim edits'' that are QLs to be applied to transition fills, because not allowing them would mean that enrollees could obtain transition fills that were unsafe or were inappropriate drug use under standard DUR reviews. This approach is consistent with our current transition policy in Manual Chapter 6, Section 30.4.8.

We propose to add a definition of ''safety-based claim edit'' to § 423.100. Our proposed definition of incorporates § 423.153(c)(2), which states that a review of each prescription must include but not be limited to:—

- Screening for potential drug therapy problems due to therapeutic duplication;
- Age/gender-related contraindications;
- Over-utilization and under-utilization;
- Drug-drug interactions;
- Incorrect drug dosage or duration of drug therapy;
- Drug-allergy contraindications; and
- Clinical abuse/misuse.

In light of our proposal described in the preceding two paragraphs, we are also specifically proposing that § 423.120(b)(3) would state that a Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary, including Part D drugs that are on a sponsor's formulary, require prior authorization, step therapy, or under a plan's drug utilization management rules, are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100.

To illustrate these standards, the following QLs are examples of safety-based edits that could be applied to transition fills:

- A claim edit that is a QL based on the maximum dose in the FDA-approved label, such as an acetaminophen limit, would meet the standard at § 423.153(c)(2)(v) regarding prevention of incorrect drug dosage.
- A QL based on the dose, dosing frequency, and/or duration of therapy limits supported by the FDA-approved label, if no clearly stated maximum dosing limits are specified in the FDA-approved label (for example, short- and long-acting opioids, would meet the standard at § 423.153(c)(2)(iii)).
- A QL that limits topical products to a reasonable quantity over time taking into consideration the indication, directions for use, and size of the area being treated would meet the standard at § 423.153(c)(2)(iii).
- A QL that supports dose optimization to promote adherence and ensure safe and appropriate utilization by reducing pill burden when multiple strengths of the same drug are available (for example, one 40 mg tablet daily instead of two 20 mg tablets daily when the appropriate dosing frequency is once daily) would meet the standard at § 423.153(c)(2)(v) to prevent incorrect drug dosage.

[169] See also Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4—Part D Drugs and Formulary Requirements.

[170] *https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf*

[171] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

We also note that claim edits to help determine Part A or B vs. Part D coverage and to prevent coverage of a non-Part D drug are permitted during a transition period, as they reflect statutory limits on Part D coverage.

We propose to make a conforming change to § 423.120(b)(3)(iii) to include a reference to QLs. We solicit comment on this proposal.

3. Minimum 108-Day Lookback Period

Under our current regulations at § 423.120(b)(3), Part D sponsors must provide for an appropriate transition process for certain enrollees. We have consistently interpreted an appropriate transition to be required for ongoing therapy—that is, when an enrollee is receiving a drug for the first time, there is nothing to transition from, and therefore a transition supply is not necessary. Therefore, in providing for appropriate transition, it is necessary for Part D sponsors to determine whether an enrollee is receiving a new prescription or a refill for ongoing therapy, and we have long recognized that distinguishing between ''new starts'' and ongoing therapy may be difficult.

As described in Section 30.4.3 of Manual Chapter 6, our longstanding Part D policy for distinguishing between new starts and ongoing therapy has been to treat all prescriptions that could qualify for a transition as ongoing therapy unless the sponsor can make the distinction at the point of sale. More recently, Section 30.4 was updated to specify that when sponsors are able to access prior drug claims history for an enrollee of an affiliated plan, a minimum of a 108-day lookback is typically needed to adequately document ongoing drug therapy. That is, if a 108-day lookback does not show claims history for the drug for the beneficiary, the Part D sponsor treats it as a first fill, and does not provide a transition supply.

A 108-day lookback for this purpose accounts for the enrollee having a quantity of a Part D drug on hand prior to requesting a subsequent fill—meaning that CMS calculates the quantity on hand by assuming the enrollee has a 20 percent remaining balance of a previously dispensed 90-day supply prior to receiving a subsequent 90-day supply leading up to their transition period. The enrollee could have a total of 108 days supply on hand to use before they would need a transition supply and no claims for the drug during that 108-day period. Thus, on day 109, the sponsor would need to look back 108 days to catch the enrollee's last refill for the drug, which demonstrates ongoing therapy.

We propose to codify our policy by requiring at § 423.120(b)(3)(vii)(A) and (B) that, if a Part D sponsor has access to prior drug claims history for the enrollee (through an affiliated plan or otherwise), the sponsor must use a minimum 108-day claims history lookback period to determine at point-of-sale whether a pharmacy claim represents a new prescription which would not require a transition fill, or ongoing drug therapy which would require a transition fill. If a Part D sponsor does not have access to prior claims history for the enrollee and cannot determine at point-of-sale whether a pharmacy claim represents a new prescription or ongoing therapy, the sponsor must treat the prescription as ongoing therapy which would require a transition fill.

4. Pharmacy & Therapeutics (P&T) Committee Role in Transition

Section 30.1.7 of Manual Chapter 6 addresses the P&T Committee's role in transition. Last updated in 2008, some of its language is outdated vis-a-vis the current transition requirements of § 423.120(b)(3). However, we do wish to codify the P&T committee's role in transition. As Manual Chapter 6 states, CMS looks to transition process submissions for assurances that a sponsor's P&T Committee will review and provide recommendations regarding the transition procedures. The manual guidance states the rationale for this policy—because a Part D sponsor's P&T committee must include a majority of members who are practicing physicians and/or pharmacists under § 423.120(b), when the sponsor's P&T committee reviews a sponsor's transition procedures, it ensures that persons with medical and pharmaceutical expertise have reviewed such procedures.

We propose to codify this policy by adding new § 423.120(b)(3)(viii) to require that the Part D sponsor's transition policies and procedures include assurances that the Part D sponsor's P&T Committee has reviewed, provided recommendations as warranted, and approved the plan's transition policies and procedures to comply with § 423.120(b)(3). We further propose to codify our current subregulatory guidance that such policies and procedures must be submitted through a process specified by CMS as part of the plan's annual bid.

5. Timing Clarifications for Transition Notices

Section 30.4.10 of Manual Chapter 6 provides guidance on transition notices, which must be sent by the Part D sponsor to the affected enrollee within 3 business days after adjudication of the temporary transition fill, in accordance with § 423.120(b)(3)(iv). We have received questions about how to calculate the three business days. While we have not previously provided specific guidance about this issue, we propose to specify in § 423.120(b)(3)(iv) that the first business day after adjudication of the transition fill—that is, the processing of the claim—counts as business day 1. For example:

- Claim adjudication occurs on either Friday, May 3, Saturday May 4, or Sunday, May 5.
- Monday, May 6 at 11:59 p.m. is the end of business day 1.
- Tuesday, May 7 at 11:59 p.m. is the end of business day 2.
- Wednesday, May 8 at 11:59 p.m. is the end of business day 3 and the deadline for sending the notice in this example.

6. Level of Care Changes

Section 30.4.7 of Manual Chapter 6 describes unplanned circumstances for current enrollees that can arise in which current drug regimens are not on sponsors' formularies. These circumstances usually involve level of care changes in which a beneficiary is changing from one treatment setting to another. For example, this includes beneficiaries who are discharged from a hospital to a home; end their skilled nursing facility Medicare Part A stay (where pharmacy charges were covered as part of the stay) and need to obtain their medications from their Part D plan thereafter; give up hospice status to revert to standard Medicare Part A and B benefits; end an LTC facility stay and return to the community; or are discharged from psychiatric hospitals with drug regimens that are highly individualized.

These admission and discharge scenarios potentially involve circumstances in which an enrollee's prescriptions are adjusted as they move through the health care system, and such adjusted prescriptions may include drugs that are not on a sponsor's formulary, or are on a sponsor's formulary but require prior authorization, step therapy, or are subject to an approved QL lower than the enrollee's current dose that is not a safety-based claim edit, as proposed at paragraph § 423.120(b)(3). Thus, these scenarios could involve interruptions in ongoing drug therapy for a Part D beneficiary.

Section 30.4.7 acknowledges that while Part A does provide reimbursement for ''a limited supply'' to

facilitate beneficiary discharge, beneficiaries need to have a full outpatient supply available to continue therapy once this limited supply is exhausted. The guidance further notes that this is particularly true for beneficiaries using mail-order pharmacy services, using home infusion therapy, or residing in rural areas where obtaining a continuing supply of drugs may involve certain delays.

For these reasons, we propose at new paragraph § 423.120(b)(3)(i)(A)(5) to require Part D sponsors to apply their transition processes to current enrollees experiencing a level of care change, such as admission or discharge from a hospital, skilled nursing facility, long-term care facility, and hospice. This would mean that, pursuant to § 423.120(b)(3), a Part D sponsor must provide for an appropriate transition process for enrollees experiencing a level of care change who are prescribed Part D drugs that are not on a sponsor's formulary, or are on a sponsor's formulary but require prior authorization, step therapy, or are, as proposed in section W.2. of this proposed rule, subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100.

However, acknowledging that a Part D sponsor may not have access to information about an enrollee's level of care changes, we propose new § 423.120(b)(3)(i)(A)(5) to specify that the sponsor would have to apply its transition process to enrollees experiencing a level of care change only if the sponsor were notified of such change by the enrollee or their representative, their prescriber, the hospital or facility, or a pharmacy before or at the time of the request for the fill referenced in § 423.120(b)(3)(iii). Such notification could be by electronic messaging.

7. LTC Emergency Supply

Section 30.4.6 of Manual Chapter 6 states, that as a matter of general practice, LTC facility residents need to receive their medications as ordered without delay. This is because the requirements for LTC facilities at § 483.45 state that the facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.70(g). Section 483.45(a) also requires that a facility provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

The State Operations Manual Appendix PP—Guidance to Surveyors for Long Term Care Facilities (Rev. 11–22–17) [172] contains guidance for complying with § 483.45. Paragraph A on page 455 of this guidance, titled ''Provision of Routine and/or Emergency Medications'' states, ''The regulation at § 483.45 requires that the facility provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident . . . Whether prescribed on a routine, emergency, or as needed basis, medications should be administered in a timely manner. Delayed acquisition of a medication may impede timely administration and adversely affect a resident's condition.''

Accordingly, our longstanding policy in section 30.4.6 has been that Part D sponsors must also cover emergency supplies of new starts of non-formulary Part D drugs for LTC facility residents, outside of any respective transition periods for them, while an exception or prior authorization request is being processed. We propose to codify this requirement. Specifically, we propose to add a paragraph (8) to § 423.120(b) that would require a Part D sponsor to cover such an emergency supply during any portion of the plan year when the enrollee did not otherwise qualify for a transition fill under § 423.120(b)(3). Additionally, we propose that for purposes of a LTC emergency fill requirement, ''non-formulary'' would have the same meaning as it does for transition fills at paragraph (b)(3)—that is, a non-formulary drug also means drugs that are on the Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization, step therapy, or are subject to a QL that is not a safety-based claim edit as defined in § 423.100 under the plan's drug utilization management rules). Also, in § 423.120(b)(8), we propose that this emergency supply must be for at least 31 days of medication, regardless of dispensing increments, unless the prescription is written by a prescriber for less than 31 days.

8. Summary of Proposals

In summary, we are proposing to codify current Part D transition guidance at § 423.120(b) as follows:

- Specify at paragraph (b)(3) that, for transition purposes, non-formulary drugs include drugs that are on the sponsor's formulary but are subject to a QL that is not a safety-based claim edit as we propose to define that term in § 423.100; and make a conforming change to § 423.120(b)(3)(iii) to include a reference to QLs.
- Add new paragraph (b)(3)(vii)(A) to require that if a Part D sponsor has access to prior drug claims history for the enrollee (through an affiliated plan or otherwise), the sponsor must use a minimum 108-day claims history lookback period to determine whether a pharmacy claim represents a new prescription which would not require a transition fill, or ongoing drug therapy which would require a transition fill. Paragraph (b)(3)(vii)(B) would state that if a Part D sponsor does not have access to prior claims history for the enrollee and cannot determine at point-of-sale whether a pharmacy claim represents a new prescription or ongoing therapy, the sponsor must treat the prescription as ongoing therapy which requires a transition fill.
- Add new paragraph (b)(3)(viii) to require that the Part D sponsor's transition policies and procedures include assurances that the Part D sponsor's P&T Committee has reviewed, provided recommendations as warranted, and approved the plan's transition policies and procedures to comply with § 423.120(b)(3), and that such policies and procedures must be submitted through a process specified by CMS as part of the plan's annual bid.
- Specify at paragraph (b)(3)(iv) that the first business day after adjudication of the transition fill counts as business day 1 for purposes of determining when a transition notice must be provided to an enrollee.
- Add new paragraph (b)(3)(i)(A)(5) to include a new group of enrollees experiencing a level of care change, to which a Part D sponsor's transition process must apply, if the sponsor is notified of such change by the enrollee or their representative, their prescriber, the hospital or facility, or a pharmacy before or at the time of the request for the fill referenced in § 423.120(b)(3)(iii).

In addition, we propose to codify our current long-term care (LTC) emergency supply guidance as follows:

- Add new paragraph § 423.120(b)(8) to codify a requirement that a Part D sponsor must cover an emergency supply of a non-formulary Part D drug for a long-term care facility resident after their respective transition period, including Part D drugs that are on a sponsor's formulary but under a plan's drug utilization management rules, require prior authorization, step therapy, or are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100.

[172] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-PP-State-Operations-Manual.pdf.*

As the foregoing describes our proposal to codify existing guidance with which we believe Part D sponsors are currently complying, we conclude that there is no additional paperwork burden for sponsors from this proposal.

We solicit comments on these proposals.

X. Update of Terminology to ''Individuals with Intellectual Disabilities'' (§ 423.154)

Following the passage of Rosa's Law (Pub. L. 111–256) in 2010, CMS updated references in CMS regulations to the term ''mentally retarded'' (MR) and replaced that term with the term ''individuals with intellectual disabilities'' (IID) in the ''Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction'' final rule which appeared in the **Federal Register** on May 16, 2012 (77 FR 29001). This global terminology change included updating the definition at § 435.1010 of individuals receiving active treatment in ''intermediate care facilities for the mentally retarded'' (ICF/MR),'' changing the term for the facility to ''intermediate care facilities for individuals with intellectual disabilities.'' However, at that time, we inadvertently neglected to update the Part D regulation at § 423.154(c), which provides a waiver for certain requirements regarding dispensing Part D drugs to individuals in intermediate care facilities (ICFs) ''for the mentally retarded . . . as defined in § 435.1010'' that otherwise apply to other types of long-term care facilities.

Additionally, in the ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' final rule which appeared in the **Federal Register** on February 12, 2015 (80 FR 7911), we updated the abbreviation in regulation text in § 423.154 from ICFs/MR to ICFs/IID, but inadvertently neglected to change the corresponding text in the regulation from which the abbreviation derives.

Consequently, we are taking this opportunity to update the current language at § 423.154(c) (that is, intermediate care facilities for the mentally retarded) with the abbreviation (that is, ICFs/IID) and the definition at § 435.1010. We propose to replace the term ''the mentally retarded'' at § 423.154(c) with ''individuals with intellectual disabilities.''

We welcome comments on this proposal.

Y. Technical Correction To Restore the Substantial Difference Requirement (§ 423.265)

We are proposing to make a technical correction to § 423.265(b)(2) to restore language on requirements for substantial differences between Medicare Part D sponsors' bids that was inadvertently removed in a recent revision of the section.

Section 1857(e)(1) of the Act authorizes us to establish contract terms that CMS finds ''necessary and appropriate.'' Section 1860D–11(d)(2)(B) of the Act requires us to promulgate ''reasonable minimum standards'' for Part D sponsors through regulations. Accordingly, we added language to the regulatory text at § 423.265(b) to require Part D bid submissions to reflect substantial differences in benefit packages or plan costs as part of the ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' final rule, which appeared in the **Federal Register** on April 15, 2010 (75 FR 19678).

Additionally, 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, which appeared in the **Federal Register** on April 16, 2018 (hereinafter referred to as the April 2018 final rule, 73 FR 16440), we reorganized paragraph (b)(2) to incorporate a general rule in paragraph (b)(2)(i) and an exception in paragraph (b)(2)(ii), the latter of which excluded enhanced alternative plan bid submissions from the substantial difference requirement.

We added language placing limits on the number of Part D plan offerings as part of the final rule titled ''Medicare and Medicaid Programs; Contract Year 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'' which appeared in the **Federal Register** on January 19, 2021 (hereinafter referred to as the January 2021 final rule, 86 FR 5864). However, the new language was incorrectly added to § 423.265(b)(2) rather than § 423.256(b)(3), and the previous regulatory text on substantial differences was inadvertently overwritten. To correct this inadvertent deletion, we propose to:

- Redesignate the regulatory text from our January 2021 final rule limiting the number of bids a Part D plan sponsor may submit currently at § 423.265(b)(2) as § 423.265(b)(3);
- Restore the language from our April 2018 final rule on substantial differences at § 423.265(b)(2)(i) and (ii); and
- Redesignate the regulatory text currently at § 423.265(b)(3) as paragraph (b)(4).

As described previously, all of the regulatory language that we propose to restore at § 423.265(b)(2) has previously undergone the full notice and comment process. This proposal would merely correct a technical error made by the January 2021 final rule.

We welcome comments on this proposal.

Z. Part D Global and Targeted Reopenings (§§ 423.308 423.346)

Pursuant to the authority under section 1860D–15(f)(1)(B) of the Act, the Secretary has the right to inspect and audit any books and records of a Part D sponsor or MA organization regarding costs provided to the Secretary. We stated in the January 2005 Part D final rule (70 FR 4194, 4316) that this right to inspect and audit would not be meaningful, if upon finding mistakes pursuant to such audits, the Secretary was not able to reopen final determinations made on payment. Therefore, we established a reopening provision at § 423.346 that would allow us to ensure that the discovery of any payment issues could be rectified. In the January 2005 Part D final rule, we established that a reopening was at our discretion and could occur for any reason within 12 months of the final determination of payment, within 4 years for good cause, or at any time when there is fraud or similar fault. We operationalized this provision by conducting program-wide reopenings (that is, global reopenings) and, when necessary, reopenings targeted to specific sponsors' contracts (that is, targeted reopenings).

In this proposed rule, we propose to codify the definitions of ''global reopening'' and ''targeted reopening.'' We also propose to modify the timeframe for performing a reopening for good cause from within 4 years to within 6 years to align with the 6-year overpayment look-back period described at § 423.360(f) and to help ensure that payment issues, including overpayments, can be rectified. In addition, we propose to codify the circumstances under which CMS will notify the sponsor(s) of our intention to perform a reopening and the requirement for CMS to announce when it has completed a reopening.

1. Summary of the Current Process

Under the current process and under § 423.346, CMS performs a reopening of a Part D payment reconciliation (that is, the initial payment determination) as a result of substantial revisions of prescription drug event (PDE) data and/or direct and indirect remuneration (DIR) data due to plan corrections, CMS corrections of systems errors, post reconciliation claims activity, and audit and other post reconciliation oversight activity. Based on our experience in the Part D program and the changes that we observed in the PDE and DIR data, we understood when we established this process that we would need to perform a reopening of the initial payment determination for every contract year.

By calendar year 2013, CMS had completed reopenings of the 2006, 2007, and 2008 Part D payment reconciliations and began our pattern of completing reopenings for subsequent Part D payment reconciliations approximately 4 years after the completion of each Part D payment reconciliation (consistent with the timing described at § 423.346(a)(2)). These reopenings included all Part D contracts that met the following criteria: (1) were in effect during the contract year being reopened, and (2) were either in effect at the time CMS completed the reopening or, if nonrenewed or terminated pursuant to § 423.507 through § 423.510 (collectively referred to as ''terminated'' for the purposes of the proposed rule), had not completed the final settlement process by the time CMS completed the reopening. CMS has referred to this type of program-wide reopening as a ''global reopening.'' See, for example, HPMS memorandum, ''Reopening of the 2006, 2007, and 2008 Part D Payment Reconciliations,'' April 2, 2012 (available at *https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-2012-qtrs-1-4*).

In addition to ''global reopenings,'' CMS has performed reopenings as part of our process to correct certain issues. We would consider performing a reopening to correct issues such as those associated with CMS-identified problems with an internal CMS file that CMS used in a Part D payment reconciliation, a coverage gap discount program reconciliation, or a reopening; CMS corrections to a PDE edit that impacted a specific plan type (for example, EGWPs); fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor; or a Part D sponsor's successful appeal of a reconciliation result. See, for example, HPMS memorandum, ''Second reopening of the 2011 Final Part D Payment Reconciliation,'' July 7, 2017 (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3*) and HPMS memorandum, ''Reopening of the 2014 Final Part D Reconciliation for Employer Group Waiver Plans (EGWPs),'' January 11, 2017 (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr1*). These reopenings are not program-wide, but rather are targeted to the Part D contracts that are impacted by the particular issue that needs to be addressed by CMS (that is, ''targeted reopenings''). The targeted reopenings are not performed on a predictable schedule, and instead are utilized by CMS in the confines on the reopening timeframes described in the current regulation at § 423.346(a)(1) through (3).

Although in our most recent experience, CMS has utilized targeted reopenings as part of our process to correct certain issues (described above), under the current process, if a particular issue was program-wide, CMS would perform a global reopening to address that issue. This global reopening could be in addition to the scheduled global reopening that CMS has performed approximately four years after the Part D payment reconciliation for that year.

2. Aligning the Timing of Reopenings to the Overpayment Look-Back Period

Pursuant to the current § 423.346(a)(2), CMS may reopen and revise an initial or reconsidered final payment determination within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening. As already discussed, this paragraph (a)(2) has set up our current global reopening schedule. CMS performs the Part D payment reconciliation (that is, the initial payment determination) for a contract year, and then within four years of announcing the completion of that reconciliation, we perform a global reopening on that contract year.

This reopening process is used to recoup overpayments associated with PDE and DIR related overpayments. Pursuant to the current overpayment provision at § 423.360(f), there is a ''look-back period'' in which a Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years. As described at § 423.360, an overpayment occurs after the ''applicable reconciliation.'' The applicable reconciliation refers to the deadlines for submitting data for the Part D payment reconciliation.

The following example illustrates the timing of look-back period. The deadlines for submitting data for the 2021 Part D payment reconciliation were in June 2022. Prior to the deadlines for submitting data for the 2021 Part D payment reconciliation, a PDE or DIR related overpayment could not exist for 2021, and the latest year for which an overpayment could occur was 2020. Therefore, prior to the deadlines for submitting data for the 2021 Part D payment reconciliation, the look-back period was 2015–2020.

This 6-year look-back period along with the 4-year reopening timeframe described at § 423.346(a)(2) results in overpayments being reported for a contract year after CMS has performed the global reopening for that contract year. Continuing from the example above, if a Part D sponsor identified a PDE or DIR related overpayment associated with contract year 2016 in May 2022 (that is, prior to the deadlines for submitting data for the 2021 Part D payment reconciliation), that overpayment falls within the 2015–2020 look-back period, and the sponsor would have reported the overpayment to CMS mid-2022. However, CMS completed the global reopening of the 2016 Part D payment reconciliation in January 2022. This discrepancy between the 4-year reopening timeframe and the 6-year overpayment look-back period results in operational challenges for CMS, discussed below.

CMS had described a process for recouping PDE and DIR related overpayments after the global reopening for the contract year at issue had been completed. In the preamble to our final rule, ''Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' 79 FR 29843 (May 23, 2014) and in subsequent subregulatory guidance, we stated that overpayments reported after the global reopening would be reported by the sponsor with an auditable estimate and that CMS would recoup the overpayment by either requesting a check or offsetting monthly prospective payments for the amount provided in the auditable estimate. See HPMS memorandum, ''Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting,'' April 6, 2018 (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/*

HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-Week1-Apr-2-6). For PDE and DIR related overpayments, that approach presents challenges primarily because sponsors have also reported PDE and DIR related underpayments after the global reopening, which we do not have a method to process other than the reopening process.

We have contemplated doing targeted reopenings to reconcile the changes in PDE and DIR data, but that also presents operational challenges. Targeted reopenings are conducted using the same payment reconciliation system that conducts the Part D payment reconciliation, the coverage gap discount program reconciliation, and the scheduled global reopening. Given the volume of reporting after the scheduled global reopening, it would be challenging to find the time and resources to run multiple targeted reopenings.

Therefore, we propose to modify § 423.346(a)(2) such that CMS may reopen and revise an initial or reconsidered final payment determination after the 12-month period (described at § 423.346(a)(1)), but within 6 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening. This proposed change will allow CMS to process all changes to PDE data and DIR data after the overpayment look-back period for a contract year. Once a contract year falls outside the look-back period, we would perform the global reopening for that contract year within the new proposed 6-year timeframe, and in doing so, would recoup the PDE and DIR related overpayments reported by sponsors for that contract year (as well as process underpayments).

Should this proposal be adopted, CMS will provide operational guidance, as we have with every regularly scheduled global reopening. The following example describes the proposed timing for performing the scheduled global reopening. The data for the 2020 Part D payment reconciliation was due June 2021. That reconciliation was completed November 2021. Assuming the current 4-year schedule, the DIR data for the contract year 2020 global reopening would be due to CMS by the end of July 2025, PDE data would be due September 2025, and the 2020 global reopening would be completed the end of 2025 or early 2026. However, the 2020 contract year remains in the overpayment look-back period through June 2027. Under the proposed 6-year timeframe, data for the 2020 global reopening would be due middle to late 2027, and the global reopening would be completed late 2027 or early 2028, after the 6-year look-back period.

3. Standards for Performing Global and Targeted Reopenings

Consistent with the existing regulation at § 423.346(a) and (d), reopenings are at CMS' discretion. Under the current process, CMS has used its discretion to perform a scheduled global reopening on a Part D payment reconciliation within the timeframe specified at § 423.346(a)(2). Given the significant time and the costs associated with conducting a reopening, it is expected that CMS will use its discretion to conduct a targeted reopening (or an additional global reopening for a program-wide issue) only under limited circumstances. We would contemplate using our discretion to perform a targeted reopening (or an additional global reopening) to correct or rectify a CMS file or CMS-created PDE edit-type issue, revise a payment determination that was based on PDE and/or DIR data that was submitted due to fraudulent activity of the sponsor or the sponsor's contractor, or pursuant to a successful appeal under § 423.350. CMS will not use its discretion to conduct a reopening to reconcile data that will be, or should have been, reconciled in the scheduled global reopening, which would include data from plan corrections, claims activity, and audits that were completed after the deadline for submitting data for the scheduled global reopening. In addition, we are unlikely to conduct a reopening solely pursuant to a sponsor's request. First, we propose that in order to be included in a reopening, a contract must have been in effect (that is, receiving monthly prospective payments and submitting PDE data for service dates in that year) for the contract year being reopened. Intuitively, if a contract was not in the reconciliation for a particular contract year, it cannot be included in the reopening of that contract year's reconciliation. Second, we propose that if CMS has sent a nonrenewed or terminated contract the ''Notice of final settlement,'' as described at proposed § 423.521(a), by the time CMS completes the reopening, described at proposed § 423.346(f), CMS will exclude that contract from that reopening. We established the proposed exclusion based on the timing of the issuance of the ''Notice of final settlement'' and completion of the reopening, as opposed to the announcement of the reopening, due to the potentially lengthy reopening process and the likelihood that the ''Notice of final settlement'' will be issued prior to CMS completing the reopening process. For example, under the current timeframe for the scheduled global reopening, CMS has typically announced in the Spring and completed the reopening in December of that year or January of the next. During that timeframe, nonrenewed or terminated contracts will likely go through the final settlement process, and as a result, will not be able to complete the reopening process. This is because, pursuant to proposed § 423.521(f), after the final settlement amount is calculated and the ''Notice of final settlement'' is issued to the Part D sponsor, CMS will no longer apply retroactive payment adjustments, and there will be no adjustments applied to amounts used in the calculation of the final settlement amount. We propose to codify these inclusion criteria at § 423.346(g).

We also propose at § 423.346(g)(2) that, specifically for targeted reopenings, CMS will identify which contracts or contract types are to be included in the reopening. This is because, as described above, targeted reopenings are targeted to the Part D contracts that are impacted by the particular issue that CMS needs to address. Therefore, in order to be included in a targeted reopening, the Part D contract must have been impacted by the issue that causes CMS to perform a reopening. To date, most targeted reopenings have been performed because of a CMS-identified issue that most sponsors were not aware of prior to CMS completing the targeted reopening. Meaning that, sponsors would not be aware of this specific inclusion criteria unless CMS informed the sponsors of the CMS-identified issue and the sponsors' contracts impacted. Therefore, we propose that CMS will notify sponsors of this specific inclusion criteria via the proposed reopening notification and/or the proposed reopening completion announcement, as described below.

4. Reopening Notification and Reopening Completion Announcement

We propose to add new paragraphs at § 423.346 to codify our existing policy regarding reopening notifications and reopening completion announcements. We propose to codify at § 423.346(e) that CMS will notify the sponsor(s) that will be included in the global or targeted reopening of its intention to perform a global or a targeted reopening—that is, the sponsor would receive prior notice of the reopening—only when it is necessary for the sponsor(s) to submit PDE data and/or DIR data prior to the reopening. In contrast, if it is not necessary for the

sponsor(s) to submit data prior to a reopening, we propose to notify the sponsor(s) only after we have conducted the reopening. For example, if CMS identifies an error in an internal CMS file that CMS used in the reconciliation or reopening, CMS may correct that file and reopen (holding all other data originally used constant), without the need for the sponsor(s) to submit PDE data or DIR data. See, for example, HPMS memorandum, ''Second reopening of the 2011 Final Part D Payment Reconciliation,'' July 7, 2017 (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%3F-2017-Qtr3*).

We propose at paragraph (e)(1) that CMS will include in the notification the deadline for submitting PDE data and/or DIR data to be included in the reopening. We also propose that the deadline to submit this data will be at least 90 calendar days after the date of the notice. Ninety days is consistent with our proposed PDE timeliness requirements at proposed § 423.325(b).

In addition, we propose at § 423.346(e)(2) that the reopening notification will include inclusion criteria in the form of a description of the contract(s) (either specifically by contract number or generally by contract-type or contract status) that will be included in the reopening. This will put a sponsor on notice of whether its contracts are included in the reopening.

We propose to codify at § 423.346(f) that CMS will announce when it has completed a reopening, including in cases where CMS issued a notice under proposed paragraph (e). This announcement is consistent with existing policy and past practice. At paragraph (f)(1), we propose to specify that CMS will provide a description of the data used in the reopening. As in past reopenings, this data could include PDE data described by the processed date on the Prescription Drug Front-end System (PDFS) response report, DIR data described by the date received in the Health Plan Management System (HPMS), as well as any other relevant data used to perform the reopening.

At paragraph (f)(2), we propose to include in the notice a statement of the contract(s) (either specifically by contract number or generally by contract-type or contract status) that were included in the reopening, consistent with proposed § 423.346(e)(2). We propose to specify which contracts or contract types are included in both notices, that is, both the announcement of the completion of the reopening and the reopening notification because, as proposed above, CMS would not issue a reopening notification when it is not necessary for the sponsor(s) to submit PDE data and/or DIR data prior to the reopening.

At paragraph (f)(3), we propose to include in the announcement of the completion of the reopening the date by which reports describing the reopening results will be available to the sponsor. In addition, at paragraph (f)(4), we propose to include the date by which a sponsor must submit an appeal, pursuant to § 423.350, if the sponsor disagrees with the reopening results.

5. Definitions of ''Global Reopening'' and ''Targeted Reopening''

We propose to adopt definitions of global reopening and targeted reopening at § 423.308. We propose that a global reopening is a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that the meet the inclusion criteria described at proposed § 423.346(g). We propose that the definition of the targeted reopening is a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsors contracts that the meet the inclusion criteria described at proposed § 423.346(g). Finally, consistent with these proposed definitions, we propose to add the terms ''global reopening'' and ''targeted reopening'' to existing § 423.346(a).

The proposals described previously are consistent with our current guidance and requirements. Nothing in this proposal places additional requirements on Part D sponsors. As such, the proposed changes to § 423.308 and § 423.346 do not place any additional burden on the Part D sponsors or their pharmacy benefit managers (PBMs). Our proposal will not change the extent to which Part D sponsors comply with the reopening process. Part D sponsors' compliance with this reopening process is evidenced by each Part D sponsor's signed attestation certifying the cost data (pursuant to § 423.505(k)(3) and (5)) that CMS uses in each of the reopenings. In addition, the burden associated with the submission of cost data is already approved under the OMB control numbers 0938–0982 (CMS–10174) and 0938–0964 (CMS–10141). Therefore, we do not believe that our proposal will result in additional burden and have not incorporated this provision in the COI section of this rule, nor are we are scoring this provision in the Regulatory Impact Analysis section because industry is already complying with this process.

AA. Part D Proposed Automatic Shipment Requirements (§ 423.505)

1. Background

An automatic shipment or automatic delivery (collectively referred to hereinafter as ''auto-ship'') service refers to the service whereby a pharmacy ships prescription refills to an individual's home when the refill is due without requiring the individual to make separate requests for each refill. Auto-ship service does not refer to the delivery of new prescription fills or prescription refills coordinated by long-term care (LTC) facilities for their residents. By ''prescription refills,'' we mean all fills of a prescription for a medication after an individual has obtained an initial fill; including both refills with the same prescription number as well as prescription renewals for the same drug, dose, and instructions with new prescription numbers. Additionally, while often employed by traditional mail-order pharmacies, some retail pharmacies also offer auto-ship services.

Auto-ship services provide an added convenience for Part D enrollees and have the potential to improve adherence by preventing interruptions in therapy resulting from late refills. However, auto-ship services can also generate waste and additional costs for Part D enrollees and the Part D program when unneeded or unwanted refills are shipped. Once a drug leaves the pharmacy, it generally cannot be returned and reused. In an effort to address concerns with the potential waste, we provided guidance in the Final CY 2014 Call Letter instructing Part D sponsors to require their network pharmacies to obtain enrollee consent prior to shipping each new prescription or prescription refill (See page 144, published on April 1, 2013, and available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf*). In effect, we were instructing Part D sponsors to prohibit their network pharmacies from providing auto-ship services because we were still requiring the individual to make separate requests for each refill.

Since the Final CY 2014 Call Letter, however, we have provided clarifications to the initial guidance, via Health Plan Management System (HPMS) memoranda and more recent Call Letters, that have gradually allowed for additional auto-ship services. For example, the subsequent guidance provided exceptions for employer-group waiver plans (EGWPs) and for new prescriptions received directly from the

prescriber for Part D enrollees with experience using auto-ship services. We applied these exceptions to pharmacies meeting certain conditions intended to balance the benefits of auto-ship services against the potential for waste and associated increased costs, such as providing that auto-ship services are for Part D enrollees that opt-in, and providing for refunds for any unwanted shipments. Most recently, we solicited feedback on proposed modifications to auto-ship services guidance as a part of the Draft CY 2020 Call Letter (See page 199 of Part 2, published on January 30, 2019, and available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf*). The proposed modifications included expectations that pharmacies would obtain annual consent from enrollees to participate in an auto-ship program, only offer an auto-ship option for refills of drugs that a Part D enrollee has been on for at least four consecutive months, send at least two reminders in advance of each shipment, and provide a full refund for any refills auto-shipped that a Part D enrollee reported as unneeded or otherwise unwanted. After receiving overwhelmingly positive comments, we announced in the Final CY 2020 Call Letter (See page 230, published on April 1, 2019, and available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf*) that, beginning in CY 2020, interested Part D sponsors could permit network pharmacies to offer opt-in, voluntary, auto-ship for refills of established therapies to further promote consistent access to medications, support medication adherence, and offer Part D enrollees additional choices in obtaining their covered Part D drugs. The final policy did not include the expectation that pharmacies obtain annual consent, or to auto-ship only to those enrollees that had been on the drug for at least four consecutive months. The guidance applied to auto-ship services for traditional multi-month mail-order supplies as well as auto-ship services for shorter day supplies from pharmacies utilizing innovative dispensing models and specialized packaging.

We have not received concerns or complaints from Part D enrollees or Part D sponsors since we issued our current guidance in the Final CY 2020 Call Letter. We are now proposing to codify these policies for auto-ship services.

Section 1860D–12(b)(3) of the Act (42 U.S.C. 1395w–112(b)(3)) authorizes the Secretary to include contract terms for Part D sponsors that are consistent with Part C as found under sections 1857(a) and 1857(d) of the Act. We are committed to ensuring consistent and reliable access to Part D drugs for Part D enrollees, and propose to codify in regulation auto-ship policies with appropriate safeguards to prevent or limit unwanted or unnecessary auto-shipped prescriptions. Specifically, we propose to add a new paragraph at § 423.505(b)(28) to require Part D sponsors to require their network pharmacies that offer auto-ship services to—

- Provide automatic shipments only to Part D enrollees that opt-in, on a drug-by-drug basis, after an initial fill;
- Provide shipping reminders prior to each shipment;
- Refund any cost sharing paid by the Part D enrollee and reverse the claim when the enrollee reports the shipment is not needed or wanted; and
- Discontinue auto-ship services when a Part D enrollee requests to opt-out or when notified that a Part D enrollee has entered a skilled nursing facility or elected hospice coverage.

2. Voluntary Participation

We propose to add new paragraph § 423.505(b)(28)(i) to require Part D sponsors to require their network pharmacies that provide auto-ship services to provide automatic shipments only to Part D enrollees that opt-in to auto-ship services, on a drug-by-drug basis, after an initial fill. Drug-by-drug means that network pharmacies would be required to document that a Part D enrollee has opted to receive auto-ship services for each specific drug. A blanket opt-in option applying across multiple drugs would not satisfy this requirement. We propose the qualifier ''after an initial fill,'' because network pharmacies should not assume the Part D enrollee would consent to auto-ship services for a specific drug at the same time as an initial fill. A period of time is needed for the Part D enrollee to initiate therapy, and establish with their prescriber whether treatment with the new drug is tolerated and to be continued. Once a Part D enrollee voluntarily selects auto-ship services for a specific drug after an initial fill, a network pharmacy could consider this Part D enrollee to have chosen to have auto-shipped all prescription refills authorized for that drug. In addition, if a provider renews a prescription for a drug for which an enrollee previously selected auto-ship services, we propose that the network pharmacy may extend the Part D enrollee's previous consent for auto-ship services to the new prescription and its authorized refills, unless instructed otherwise by the Part D enrollee, their provider, or an authorized representative. In turn, auto-ship services may be cancelled by a Part D enrollee, their provider, or an authorized representative.

We welcome comments on this proposal.

3. Enrollee Notification

We propose to add new paragraph § 423.505(b)(28)(ii)(A)) to require Part D sponsors to require their network pharmacies to provide a minimum of two (2) shipping reminders to the Part D enrollee prior to shipment through auto-ship services. Such reminders would need to be received prior to shipment so that a Part D enrollee can modify or cancel an order, if needed. Part D sponsors may specify an approximate shipping date range (for example, 2–3 calendar days) in lieu of an exact date in shipping reminders.

We also propose to add new paragraph § 423.505(b)(28)(ii)(B) to specify that network pharmacies must provide the shipping reminders by hard copy mailing, telephone, electronic delivery, or other comparable means of communication such as a fax machine. The method of delivery should be based on the Part D enrollee's stated preference when feasible. A missed call with no message left, bounce-back email messages, or returned direct mailings would not count as successful shipping reminders because they indicate that the enrollee never received the reminder.

Additionally, we propose to add for § 423.505(b)(28)(ii)(C) the requirement that all types of reminders must, at a minimum, include the name of the Part D drug, any applicable cost sharing, the scheduled shipping date, instructions on how to cancel the pending automatic shipment, and instructions on how to opt-out of any future automatic shipments. In turn the pharmacy would be required to honor the request to cancel the specified drugs from further auto shipment.

We welcome comments on this proposal.

4. Refund Policy

We propose to add new paragraph § 423.505(b)(28)(iii) to require Part D sponsors to require their network pharmacies that provide auto-ship services to refund any cost sharing paid by the Part D enrollee for any shipped prescriptions that such Part D enrollee reports as unneeded or otherwise unwanted, regardless of whether the drug is returned to the pharmacy, and reverse the claim. Part D sponsors would be required to delete the associated Prescription Drug Event (PDE) for these reversed claims. We

believe a full refund policy is necessary to protect the Part D enrollee from the potential cost, safety risk, and inconvenience of unneeded or unwanted prescriptions being filled, charged, and shipped. Unlike a retail pharmacy setting where a Part D enrollee can review a medication, including its use and cost, prior to purchasing, auto-ship services remove the opportunity for the Part D enrollee (or their authorized representative) to provide a final in-person check and confirmation of understanding prior to purchase. In addition, should a Part D enrollee report a drug enrolled in auto-ship services as unneeded or unwanted, this presents an opportunity for discussion between the network pharmacy and the Part D enrollee on continuing auto-ship services for the drug in question, or any other drugs enrolled in auto-ship services for the Part D enrollee. Given the proposed reminder requirements discussed in section IV.AA.3 of this proposed rule, combined with the fact that we have received no complaints since our current guidance on auto-ship services has been in effect, we believe network pharmacies are well positioned to evaluate the appropriateness and safety of auto-ship services in collaboration with Part D enrollees. Moreover, we believe the lack of complaints received are also an indication that the potential for abuse of such a refund policy is low.

We welcome comments on this proposal.

5. Discontinuation

We propose to add new paragraph § 423.505(b)(28)(iv) to require Part D sponsors to require their network pharmacies that offer auto-ship services to discontinue auto-ship services if A) the enrollee requests to opt-out of automatic shipments or B) the network pharmacy receives notification that a Part D enrollee entered a skilled nursing facility (SNF) or elected hospice. Notification that an enrollee has entered a SNF or elected hospice coverage may come via the Part D enrollee, the Part D enrollee's provider, the Part D enrollee's authorized representative, or the Part D sponsor. A Part D sponsor could receive such information via a data system, such as daily Transaction Record Reports (TRR) or the MARx system. Section 1860D–2(e)(2)(B) of the Act states that a drug prescribed to a Part D eligible individual cannot be considered a covered Part D drug if payment for such drug is available (or would be available but for the application of a deductible) under Part A or B for that individual as prescribed and dispensed or administered, such as during an inpatient hospital stay or home health episode. Thus, it is imperative that a network pharmacy discontinue auto-ship services for any drug that should be covered under Parts A or B due to a change in the Part D enrollee's status that has drug coverage implications.

We welcome comments on this proposal.

6. Summary of Proposals

In summary, consistent with our longstanding subregulatory guidance, we are proposing to codify in regulation at new paragraph § 423.505(b)(28) the following requirements for auto-ship services that Part D sponsors would be required to include in their network pharmacy contracts:

- The proposed § 423.505(b)(28)(i) would require that participation is voluntary;
- The proposed § 423.505(b)(28)(ii)(A) would require a minimum of two (2) shipping reminders prior to shipment, and § 423.505(b)(28)(ii)(B) would require that all types of reminders include all relevant information, such as the name of the Part D drug, any applicable cost sharing, the scheduled shipping date, instructions on how to cancel the pending automatic shipment ; and instructions on how to opt-out of any future automatic shipments;
- The proposed § 423.505(b)(28)(iii) would require a refund policy; and
- The proposed § 423.505(b)(28)(iv) would require discontinuation of auto-ship services if the network pharmacy receives a request from the enrollee, enrollee's prescriber, or authorized representative to opt-out of automatic shipments or notification that the Part D enrollee entered a skilled nursing facility or elected hospice coverage.

Additionally, as discussed in the preamble to this section, we have been monitoring compliance to this policy by monitoring complaints from both Part D sponsors and Part D enrollees. Consequently, there is no additional paperwork burden associated with codifying this longstanding policy.

We solicit comments on these proposals.

AB. Part D Subcontractors May Terminate Only at the End of a Month (§ 423.505)

At § 423.505(i), we propose to require Part D sponsors to include a provision in certain contracts with first tier, downstream, and related entities (FDRs) (as defined at § 423.501) that the FDR may terminate its contract only at the end of a calendar month after providing at least 60 days' prior notice. Specifically, we propose that this prior notice be required in contracts with FDRs that perform critical functions on the sponsor's behalf, as discussed below. We believe this change is necessary to protect beneficiaries from disruptions in receiving Part D benefits and to protect the Part D program from incurring additional financial liability.

Part D sponsors contract with FDRs to perform many of the services critical to the operation of the Part D program. For example, FDRs administer formularies, process beneficiary enrollments into plans, contract with pharmacies, process Part D claims at the point of sale, and administer enrollee appeals and grievance processes. Many Part D sponsors do not have the internal capability to take over administration of these functions from their FDRs on short notice. If an FDR ceases operations under a contract, enrollees in an affected plan may therefore be left without access to their Part D benefits until the sponsor is able to make alternative arrangements.

For these reasons, CMS has a critical interest in ensuring Part D sponsors' contracts with these FDRs protect beneficiaries and the program. We have codified a variety of requirements for sponsors' relationships with FDRs at § 423.505(i). For instance, we require that contracts protect enrollees from liability for fees that are the responsibility of the Part D sponsor (§ 423.505(i)(3)(i)) and that the FDR must provide services in a manner that is consistent with the Part D sponsor's contractual obligations (§ 423.505(i)(3)(iii)). These requirements promote consistent and competent administration of the Part D program.

Occasionally, Part D sponsors face financial difficulties so severe that they may stop paying FDRs for services provided under their Part D contracts. Such difficulties may also cause sponsors to be placed into receivership or bankruptcy. In response to such developments, an FDR may terminate its contract with the Part D sponsor or, in the case of FDRs that administer claims at point of sale, stop paying claims to prevent or minimize operating losses. Such actions may be prompted by overdue reimbursement from the sponsor or anticipated payment stoppages and can occur in the middle of a month, depending on the termination notice terms in the sponsor's contract with the FDR. Fortunately, such mid-month terminations are rare. However, when they occur, they can result in significant disruptions for enrollees, including a lack of access to needed prescriptions through their Part D plan. For instance, a PDP contract terminated in the middle

of March 2021 due, in part, to their PBM terminating its contract mid-month for nonpayment. This disrupted care for almost 40,000 beneficiaries and forced CMS to incur additional expense to ensure that all beneficiaries had continuous coverage for the month of March.

Mid-month terminations can also result in CMS incurring additional costs. CMS makes prospective monthly capitation payments to Part D sponsors, as provided in section 1860D–15(a)(1) of the Act and codified in § 423.315(b). When an FDR performing critical functions on a sponsor's behalf terminates a contract mid-month, CMS has already paid the sponsor for the services that the FDR was supposed to render for the remainder of that month. To protect beneficiaries from suffering further harm, CMS may find it necessary to terminate a sponsor's contract pursuant to § 423.509 or come to terms for a mutual termination pursuant to § 423.508. CMS reassigns affected beneficiaries to other Part D plans in the same service area when such terminations occur at any time other than the end of a contract year. When these reassignments occur mid-month, CMS makes a full prospective payment for that month to the plan into which enrollees are reassigned, so that CMS pays twice for the same month. For example, if contract 1 terminates effective May 15 and CMS reassigns enrollees to contract 2, CMS would pay contract 2 for the full month of May even though it already paid contract 1 for the month of May. CMS has authority under § 423.509(b)(2)(ii) to recover the prorated share of the capitation payments made to the Part D sponsors covering the period of the month following the contract termination, but as a practical matter, a contract terminated due to financial difficulties usually does not have the funds available to repay CMS. Nor is CMS able to make a prorated monthly payment to the contract into which enrollees are reassigned.

To protect beneficiaries and the Part D program from the consequences of mid-month terminations of certain FDR contracts, we propose to establish at § 423.505(i)(6) a requirement that all Part D sponsors' contracts with FDRs that perform certain key Part D functions require a minimum of 60-days' prior notice of termination with an effective date that coincides with the end of a calendar month. We are adopting this change pursuant to our authority at section 1857(e) of the Act, made applicable to Part D through section 1860D–12(b)(3)(D), which authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate and not inconsistent with the Part D statute. This proposed policy is consistent with the existing requirement that FDRs must comply with Part D requirements and support the sponsor's performance of its Part D functions, including ensuring access to covered Part D drugs under § 423.120(a), as required at § 423.505(i)(3)(iii) and (iv). Since Part D sponsors are paid prospectively and in units of no less than one calendar month, their subcontractors should be able to negotiate arrangements with their sponsors to access to covered Part D drugs in no less than 1-month increments by, for example, requiring sponsors to provide a surety bond to compensate the FDR in the event of the sponsors' fiscal insolvency. We do not believe that this will result in significant additional expense for sponsors because mid-month terminations have been very rare to date.

The proposed provision at new paragraph (6) will require the contract between a Part D sponsor and an FDR providing certain functions to state that a contract termination could only occur after a 60-day notice period and have an effective date that coincides with the end of a calendar month. The functions for which this requirement would apply would be:

- Authorization, adjudication, and processing of prescription drug claims at the point of sale;
- Administration and tracking of enrollees' drug benefits in real time;
- Operation of an enrollee appeals and grievance process; and
- Contracting with or selection of prescription drug providers (including pharmacies and non-pharmacy providers) for inclusion in the Part D sponsor's network.

All of these functions are critical to beneficiaries maintaining access to Part D drugs and ensuring that they pay appropriate out of pocket costs. The disruption of any one of these functions could result in beneficiaries not receiving necessary drugs or incurring unnecessary costs.

We solicit comments on this proposal.

AC. Application of 2-Year Ban on Reentering the Part D Program Following Non-Renewal (§§ 423.507 and 423.508)

We are proposing to amend §§ 423.507(a)(3) and 423.508(e) to clarify that the prohibition on PDP sponsors that non-renew or mutually terminate a contract receiving a new PDP contract for 2 years applies at the PDP region level. That is, if a sponsor non-renews or mutually terminates a PDP contract, the two-year exclusion would only prohibit them from receiving a new or expanded PDP contract in the PDP region(s) they exited and would not prevent them from receiving a new or expanded contract in another region(s). We are also proposing to clarify that that the 2-year exclusion applies whenever a PDP sponsor terminates all of its benefit packages (PBPs) in a PDP region, commonly known as a ''service area reduction,'' even if they continue to serve other PDP regions under the contract.

Under current regulations at §§ 423.507(a)(3) and 423.508(e), Part D sponsors that non-renew or mutually terminate their contracts with CMS are ineligible to enter into a new Part D contract for two years following the non-renewal, absent circumstances that warrant special consideration. CMS adopted the two-year exclusion at the beginning of the Part D program in 2006 in order to implement the requirements of section 1857(c)(4) of the Act, made applicable to the Part D program by section 1860D–12(b)(3)(B) of the Act. The 2-year exclusion following contract non-renewal promotes stability in the Part D program, as the additional period of contracting ineligibility causes organizations to consider more than just the year-to-year fluctuations in the Part D market in deciding whether to discontinue their participation in the program.

Given the significance of plan availability on a per region basis under the Part D statute, it makes sense to treat each PDP multiregion contract as, in effect, a set of distinct contracts, one for each PDP region, when CMS is taking action to protect market stability. For example, pursuant to § 423.859(a), CMS is required to make available to each beneficiary the choice of at least two Part D plans that serve the area in which they reside. At least one of those plans must be a PDP. Also, each PBP may only serve one PDP region. PDP sponsors submit separate bids for each PDP region. CMS uses those region-specific bids to determine the regional premium benchmarks and identify PBPs into which LIS beneficiaries will be automatically enrolled. As such, a PDP sponsor exiting or reentering one region has little or no effect on the market for PDP products in any other region.

Applying the 2-year exclusion at the PDP region level would sufficiently promote the market-stabilizing purpose of the exclusion by prohibiting PDP sponsors from non-renewing all their plans in a region and returning to the same market after only one year of absence from the program. We believe the 2-year exclusion as applied at the

regional level would prevent sponsors from undermining the nondiscrimination requirements at section 1860D–11(e)(2)(D)(i) of the Act by, for example, terminating PBPs in a region so they would no longer receive LIS auto-enrollment. If the two-year exclusion were not applied at the regional level, the effective penalty for tying Part D sponsors' participation in Part D solely to serve one segment of beneficiaries (that is, LIS eligible) would be only year's absence from offering plans in that region, rather than two. However, these same concerns do not apply across regions. A sponsor that non-renews a plan receiving LIS auto-enrollments in one region that wishes to enter a different region the next year would not simply be seeking to enroll more desirable beneficiaries who had declined to enroll in their previous plan; instead, they would be competing in a completely different market. Therefore, we see no reason to prohibit sponsors that non-renew their plans in one region from offering plans in a new region before the 2-year exclusion period elapses.

We believe the effective administration of the Part D program is best served by promoting stability at the PDP region level and preventing sponsors exiting and re-entering regions each year, which may cause disruption to the regional PDP offerings. We do not believe that we need to prohibit sponsors from entering new regions for two years after they have opted to exit other regions in order to accomplish this goal. Therefore, we propose to modify §§ 423.507(a) and 423.508(e).

We propose to modify § 423.507(a)(3) as follows:

- Revising paragraph (3) to add regulatory text clarifying that the requirements in this paragraph pertain to PDP sponsors' ineligibility to enter into a contract for two years;
- Redesignating paragraph (a)(3) regarding the current regulatory requirement regarding a 2-year contracting ban following non-renewal of a PDP contract as new paragraph (a)(3)(i);
- Adding language to new paragraph (a)(3)(i) stating that CMS cannot enter into a new contract in the PDP region or regions served by the non-renewing contract;
- Adding new paragraph (a)(3)(ii) to authorize CMS to make organizations that non-renew all of their PBPs in a PDP region ineligible to have plan bids approved again in that region for 2 years; and
- Adding new paragraph (a)(3)(iii) exempting new EGWP PBPs from the two year ban.

Similarly, we propose to apply our policy limiting the offering of plans at the PDP region level for 2 years to mutual terminations under § 423.508. We propose to add a sentence to the existing regulatory text at paragraph (e) stating that a mutual termination of participation in a PDP region makes a PDP sponsor ineligible to apply for qualification to offer new plans in that region for 2 years. While we already require sponsors seeking a mutual termination to agree not to apply for a new contract for two years, we believe that the same concerns that support applying the 2-year exclusion for non-renewals at the regional level pertain to mutual terminations. Allowing a sponsor that mutually terminates a contract in one PDP region to apply for a new contract in another PDP region does not incentivize the market-destabilizing practice of entering and exiting the PDP market in rapid succession. Therefore, we believe our application of the 2-year exclusion should be consistent between non-renewals and mutual terminations.

We note that this proposed provision would not apply to a PDP sponsor's non-renewal of its EGWP plans since those plans do not affect the availability of plan choices to beneficiaries or the number of plans that qualify for automatic LIS enrollments. We are also not concerned that non-renewal of EGWP plans would be driven by a sponsor's attempt to engage in adverse selection because EGWP plans are subject to contract negotiation between employers and sponsors and are not open to enrollment to all beneficiaries in the service area.

We solicit comments on these proposals.

AD. Crosswalk Requirements for Prescription Drug Plans (§ 423.530)

1. Overview and Summary

We propose to codify, with modifications, the current process and conditions under which PDP sponsors can transfer their enrollees into a different PDP's plan benefit packages (PBPs) from year to year when such enrollees have made no other election. This process is known as a ''plan crosswalk'' and does not apply to enrollees in employer group health or waiver plans. Our proposal defines plan crosswalks and crosswalk exceptions, codifies the circumstances under which enrollees can be transferred into different PDP PBPs from year to year, establishes the circumstances under which enrollees can be transferred into PDP PBPs offering different types of prescription drug coverage (''basic'' or ''enhanced alternative'' coverage), establishes the circumstances under which enrollees can be transferred due to contract consolidations of PDPs held by subsidiaries of the same parent organization, and provides protections against excessive premium increases resulting from crosswalks. We also propose to limit the ability of PDP sponsors to create new PDP PBPs to replace non-renewing PBPs under certain circumstances.

We request comment on whether and under what circumstance we should permit crosswalks from PBPs offering basic prescription drug coverage to PBPs offering enhanced prescription drug coverage, whether we should require sponsors that non-renew an enhanced alternative PBP while continuing to offer individual market coverage in the same PDP region to crosswalk affected beneficiaries into another PBP, and on limitations we should place on premium and cost increases for enrollees who are crosswalked between different PBPs. We are particularly interested in how best to balance avoiding gaps in prescription drug coverage, preserving beneficiary choice and market stability, and preventing substantial increases in costs to beneficiaries resulting from crosswalks.

Finally, we propose to codify the current procedures that a Part D sponsor must follow when submitting a crosswalk or crosswalk exception request.

2. Summary of Current PDP Crosswalk Policy

CMS has set forth its current PDP crosswalk policy in ''Guidance for Prescription Drug Plan (PDP) Renewals and Nonrenewals'' (hereinafter referred to as the PDP Renewal and Nonrenewal Guidance), issued in April 2018 and posted the CMS website at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Guidance-for-Prescription-Drug-Plan-PDP-Renewals-and-Non-Renewals-.pdf*. We developed the guidance to prevent beneficiary disruptions when a PDP sponsor discontinues PBPs and to allow the consolidation of PDP contracts of subsidiaries of the same parent organization. We also developed guidance related to continuation of enrollment in renewing PDP PBPs in order to facilitate ''evergreen'' enrollments, as required by sections 1851(c)(3)(B) and 1860D–1(b)(1)(B)(ii) of the Act, by not requiring additional enrollment transactions when a PBP renews in a new plan year.

Consistent with the requirement in sections 1851(c)(3)(B) and 1860D–

1(b)(1)(B)(ii) of the Act that an individual who has elected a plan is considered to make the same election until the individual changes an election or the plan is discontinued in the area in which the individual resides, enrollees remain in a renewing PBP for the following year if they do not make another election (or opt to discontinue Part D coverage). CMS requires the PBP's plan ID number to remain the same, and beneficiaries remain enrolled in the PBP unless they make another election.

If a Part D sponsor discontinues a PBP but continues to offer individual market coverage under the same PDP contract, CMS currently ''crosswalks'' enrollment from the non-renewing PBP into another active PBP under the same contract. This means that beneficiaries enrolled in the non-renewing PBP during the current plan year will be enrolled in another surviving PBP offered under the same contract the following year unless the beneficiary selects alternative coverage during the Annual Election Period (AEP). These plan crosswalks are referred to as ''consolidated renewal'' crosswalks. We use consolidated renewal crosswalks primarily to prevent beneficiaries from losing Part D coverage, as past experience indicates that about 20 percent of beneficiaries enrolled in Part D plans that non-renew without a subsequent plan crosswalk fail to select new coverage. In those cases, the beneficiaries not only lose Part D coverage, but also are subject to the Part D late enrollment penalty. We also use plan crosswalks in these situations in order to prevent plans from ''dumping'' beneficiaries who are high cost or whom the organization otherwise no longer wishes to cover.

Consolidated renewal crosswalks occur only with respect to non-renewing PBPs offering enhanced alternative coverage, as defined at § 423.100. Consistent with § 423.104(f)(2), we do not permit organizations to non-renew a PBP offering basic prescription drug coverage, as defined at § 423.100, unless they are non-renewing all individual market PBPs in a PDP region because a basic prescription drug plan offering is a requirement in order for a sponsor to offer enhanced alternative coverage within the same service area. In consolidated renewal crosswalks, sponsors may transfer affected enrollees into a PBP offering either enhanced alternative or basic prescription drug coverage. The enrollment of a non-renewing PBP is not ''split'' among multiple PBPs—that is, all beneficiaries enrolled in a non-renewing PBP are crosswalked to the same PBP in the following year.

If a Part D sponsor or multiple Part D sponsors under a single parent organization (as defined in § 423.4) operate multiple PDP contracts that they wish to consolidate in the following contract year, we permit plan crosswalks between the PBPs of the non-renewing contract(s) and the PBPs in the surviving contract. These plan crosswalks are referred to as ''contract consolidation'' crosswalks. We do not permit plan crosswalks between PBPs under different PDP contracts held by subsidiaries of different parent organizations. We currently encourage contract consolidations when multiple subsidiaries of a parent organization offer individual market PDP coverage in the same region(s) in order to promote meaningful choices and competition in the PDP market. We are proposing in section III.V. of this proposed rule to limit the number of PDP contracts a parent organization may offer through its subsidiaries to one per PDP region, but we do not think this proposal will cause significantly more contract consolidations because, historically, few parent organizations have declined to consolidate contracts in this situation.

All the enrollment in a non-renewing contract subject to contract consolidation is crosswalked into the surviving contract. The surviving PDP contract must offer individual market plans in all the PDP region(s) covered by the non-renewing contract(s). As with consolidated renewal crosswalks, enrollment from a non-renewing PBP is not ''split'' into multiple PBPs and all enrollees from non-renewing enhanced alternative PBPs are transferred into another PBP offering either enhanced alternative or basic coverage.

Unlike with consolidated renewal crosswalks, contract consolidation crosswalks can involve the non-renewal of PBPs offering basic coverage. For contract consolidation crosswalks, enrollees in non-renewing PBPs offering basic coverage are crosswalked into the PBP in the surviving contract that offers basic coverage. We do not permit contract consolidation crosswalks from PBPs offering basic coverage to PBPs offering enhanced alternative coverage, in order to protect beneficiaries receiving low income subsidies (''LIS'') from unexpected cost increases. A portion of the premium for an enhanced alternative PBP is supplemental premium. Under § 423.780(b)(1)(i), the LIS can only be used for the portion of the monthly beneficiary premium attributable to basic coverage. This does not include the amount attributed to supplemental coverage for enhanced alternative plans. Any LIS-eligible individuals enrolled in a non-renewing PBP offering basic prescription drug coverage that were transferred into a PBP offering enhanced alternative coverage, and who did not change their election, might therefore have to pay more than they would for a PBP offering basic prescription drug coverage even if the enhanced alternative PBP had a lower overall premium.

3. Proposed General Rules for Plan Crosswalks (§ 423.530(a))

Section 1860D–1(b)(1)(B) of the Act requires the Secretary to use rules similar to and coordinated with the rules for enrollment, disenrollment, termination, and change of enrollment in MA–PD plans under certain provisions of section 1851 of the Act. Therefore, in proposing to codify general rules for plan crosswalks, we seek both to maintain current policy and, to the extent possible, be consistent with the requirements for MA plan crosswalks codified at § 422.530 in the final rule published in the January 19, 2021 **Federal Register** (CMS–4192–F2) (86 FR 5864).

At § 423.530(a)(1), we propose to define a plan crosswalk as the movement of enrollees from one PDP PBP to another PDP PBP. This definition is consistent with current policy and with the definition of crosswalks for MA plans, codified at § 422.530(a)(1).

We propose at § 423.530(a)(2)(i) through (iii) to adopt the crosswalk prohibitions in current CMS subregulatory guidance, described in the PDP Renewal and Nonrenewal Guidance. First, we propose to prohibit crosswalks between PBPs in different PDP contracts unless the PDP contracts are held by the same Part D sponsor or by sponsors that are subsidiaries of the same parent organization. Second, we propose to prohibit crosswalks that split enrollment of one PBP into multiple PBPs. Third, we propose to prohibit crosswalks from PBPs offering basic coverage to PBPs offering enhanced alternative coverage.

In the past, organizations have sought exceptions to the prohibition of basic-to-enhanced alternative crosswalks on the grounds that one of the available enhanced alternative PBPs is lower cost or otherwise a better alternative for enrollees in a non-renewing basic PBP than the available basic PBP. These requests come in the context of proposed contract consolidations crosswalks and, because CMS prohibits PDP contracts from offering more than one PBP offering basic coverage in a region under § 423.265(b)(2), there would only be one option for the enrollees in non-renewing basic PBP to be transferred into. PBPs offering basic

prescription drug coverage can vary widely in premium and estimated out of pocket costs. Enhanced alternative PBPs sometimes offer lower premiums than basic PBPs under the same contract. However, as discussed previously in section IV.AD.2. of this proposed rule, a portion of the premium for an enhanced alternative PBP is the ''supplemental'' premium and any LIS-eligible individuals transferred from a basic to an enhance PBP might therefore have to pay more than they would in the available basic PBP, even if the enhanced alternative PBP has lower overall premium. Therefore, we propose to continue our current policy in order to protect LIS-eligible beneficiaries from unanticipated premium increases.

We solicit comments on whether and under what circumstances to allow crosswalks from PBPs offering basic prescription drug coverage to enhanced alternative coverage. For instance, should CMS allow plan crosswalks under these circumstances if the premiums and/or estimated total beneficiary cost of the plan offering enhanced alternative coverage would be substantially lower than for the plan offering basic coverage. CMS is interested in how and to what extent permitting such crosswalks would affect the market for basic prescription drug coverage. CMS is particularly interested in how such crosswalks could be administered in a way that protects LIS-eligible beneficiaries from premium and other cost increases.

Plan crosswalks often occur in the context of contract renewals and non-renewals. We propose at § 423.530(a)(3) to require sponsors seeking crosswalks to comply with rules in §§ 423.507 and 423.508 governing non-renewals and contract terminations, respectively. This requirement is consistent with the requirement for MA plan crosswalks codified at § 422.530(a)(3).

We propose at § 423.530(a)(4) to make clear that only enrollees eligible for enrollment under § 423.30 can be crosswalked from one PBP to another. Individuals who are not eligible for Part D enrollment cannot be enrolled in a Part D plan, so CMS cannot allow crosswalks of non-eligible individuals into new Part D plans.

Finally, we propose at § 423.530(a)(5) to continue to allow enrollees in employer group health or waiver PBPs to be transferred between PBPs in accordance with the usual process for enrollment in employer group health or waiver plans, rather than in accordance with the proposed provisions of § 423.530. This proposal ensures that the process for enrollment in employer group health or waiver plans is not disrupted by this proposed rule.

We solicit comments on these proposals.

4. Mandatory Crosswalks (§ 423.530(b))

We propose at § 423.530(b)(1) and (2) to require enrollees in PDP PBPs that are renewing to be transferred into the same PBP for the following contract year. This is consistent with the current process summarized for renewal plans in the PDP Renewal and Nonrenewal Guidance. This requirement would continue to apply to PBPs offering both enhanced alternative and basic coverage. The proposed requirement continues to facilitate evergreen enrollment as required by section 1851(c)(3)(B) of the Act. The proposal is also consistent with the requirements for MA renewal crosswalks codified at § 422.530(b)(1)(i).

We solicit comment on this proposal.

5. Plan Crosswalk Exceptions (§ 423.530(c))

We propose at § 423.530(c) to classify consolidated renewal and contract consolidation crosswalks as ''crosswalk exceptions.'' We propose to define ''consolidated renewals'' and ''contract consolidations'' consistent with the current policy described previously in section IV.AD.2. of this proposed rule. We propose to codify our current policy for the two types of plan crosswalk exceptions with some modifications.

For consolidated renewals, we propose to codify current policy at § 423.530(c)(1) with four major modifications that balance concerns for beneficiaries in non-renewing plans losing coverage with concerns about market stability and limiting unexpected premium increases. As we state in the PDP Renewal and Nonrenewal Policy, we currently expect sponsors that non-renew a PBP while continuing to offer individual market plans in the PBP's service area to crosswalk affected enrollees into a renewing PBP. As noted previously in section IV.AD.2. of this proposed rule, in recent years about 20 percent of beneficiaries in non-renewing plans that were not crosswalked failed to select new Part D coverage. These beneficiaries not only lose Part D coverage, but also may be subject to higher premiums when they reenroll in Part D because of the late enrollment penalty required under § 423.46. CMS has also sought to prevent sponsors from engaging in adverse selection by discontinuing a PBP, dropping its enrollees, and immediately starting a new PBP with the intention of attracting lower cost or otherwise more desirable enrollees.

However, in recent years, some plan crosswalks in these situations have resulted in premium increases of as much as 381 percent. In 2021, the median premium increase for such crosswalks was over 234 percent. While not every consolidated renewal crosswalk results in a premium increase, and increases are typically much smaller than those experienced in 2021, such large premium increases create a significant burden for beneficiaries. CMS has received significant complaints from beneficiaries who were surprised by large premium increases following a crosswalk. Affected contracts had more complaints than other contracts in the first three months after enrollees were crosswalked. To address this concern, we propose requirements for consolidated renewals that would reflect our current subregulatory policy, but with four significant differences.

First, we propose at § 423.530(c)(1) to allow, but not require, plan crosswalks in consolidated renewal scenarios. PDP sponsors could request a crosswalk of enrollment from a non-renewing PBP to another PBP under the same contract, provided it meets the requirements we are proposing.

We propose at § 423.530(c)(1)(i) through (iv) to codify provisions of our current policy for consolidated renewal crosswalks:

- The plan ID for the upcoming contract year PBP must be the same plan ID as one of the PBPs for the current contract year;
- The PBPs being consolidated must be under the same PDP contract;
- A PBP offering basic prescription drug coverage may not be discontinued if the PDP contract continues to offer plans (other than employer group waiver plans) in the service area of the PBP; and
- Enrollment from a PBP offering enhanced alternative coverage may be crosswalked either into a PBP offering either enhanced alternative or basic prescription drug coverage.

Our second major proposed change from current policy, at § 423.530(c)(1)(v), is that when a PDP sponsor chooses to crosswalk in a consolidated renewal scenario, to require enrollees from non-renewing PBPs offering enhanced alternative coverage to be crosswalked into the PBP that will result in the lowest premium increase. We intend for this requirement to minimize the premium increases experienced by beneficiaries who are crosswalked to new PBPs under a consolidated renewal crosswalk. Under

this proposed requirement, we would permit an otherwise allowable plan crosswalk into any eligible PBP that offered the same or lower premium compared to the nonrenewing plan, but would not allow a crosswalk into a PBP with a $30 higher premium if an eligible plan with a $10 higher premium were available. We recognize that premiums are not the only aspect of a PBP's structure that affect costs to beneficiaries or the beneficiary experience. The PBP's formulary and cost-sharing structure are also important elements affecting beneficiary costs. However, premiums for a PBP are the same for every enrollee and are therefore the most straightforward factor to use to protect enrollees from unexpected cost increases. We are soliciting comments on whether we should use other factors, such as differences in estimated out of pocket costs (OOPC) between the non-renewing and surviving PBPs, rather than simply the difference in plan premiums, to determine whether approving a plan crosswalk exception is the best option for enrollees in a non-renewing PBP. We are also requesting comments on whether to allow plan crosswalks to a higher premium plan if the difference between the higher premium plan and the lower premium plan is less than a certain dollar amount—for example, should CMS permit a crosswalk to a higher premium surviving PBP despite the availability of a lower premium surviving PBP if the difference between the premiums is less than a fixed dollar amount.

Third, we propose at § 423.530(c)(2)(vi) to prohibit plan crosswalks for consolidated renewals if the crosswalk would result in a premium increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), compared to the current year premium for the non-renewing PBP. CMS does not currently explicitly limit premium increases for renewing PBPs; however, CMS does have the authority under section1860D–11(d)(3) of the Act and § 423.265(b)(3) to decline to approve a bid that proposes significant increases in cost sharing or decreases in benefits. CMS negotiates with sponsors pursuant to this authority in order to limit increases in cost sharing or decreases in benefits, but not to explicitly limit premium increases.

Renewing PBPs therefore sometimes experience high premium increases. Despite this, in the past two years a larger share of consolidated renewal crosswalks have had premium increases of 100 percent or more compared to renewal PBPs. Only 0.8 percent of 906 PDP PBPs renewing for 2021 and 1.8 percent of 729 PBPs renewing for 2022 had premium increases greater than 100 percent. By contrast, 94.3 percent of 35 consolidated renewal crosswalks for 2021 and 29.6 percent for 2022 had premium increases greater than 100 percent.

Premium changes are also more variable year-to-year for consolidated renewal crosswalks. For the past 5 years, the average premium change for renewal PBPs ranged from an increase of 3.3 percent in 2019 to an increase of 15.9 percent in 2022. In the same time period, consolidated renewal crosswalks resulted in average premium changes that ranged from a decrease of 38.7 percent in 2019 to an increase of 229.5 percent in 2021. The data is summarized in Table 3.

TABLE 3: PREMIUM CHANGES FOR RENEWING PDP PDPS COMPARED TO CHANGES FOR CONSOLIDATED RENEWAL AND CONTRACT CONSOLIDATION CROSSWALKS

	Mean Premium Change for Renewal PDP PBPs	Mean Premium Change for Consolidated Renewal Crosswalks	Mean Premium Change for Contract Consolidation Crosswalks
2017-2018	11.6%	-7.6%	No Crosswalks
2018-2019	3.3%	-38.7%	29.2%
2019-2020	7.8%	-27.1%	No Crosswalks
2020-2021	7.4%	229.5%	No Crosswalks
2021-2022	15.9%	46.4%	47.1%

Because of the compressed time frames between bid submission and approval, CMS would base its assessment of premiums for the following plan year on information received with the initial bids on the first Monday in June. Bids are subject to change during the bid negotiation process, so a premium increase that appears acceptable in June may be higher by the time final bids are approved in August. However, the timing of plan crosswalk exceptions and bid review prevent CMS from basing crosswalk exception approvals on final bid amounts. Based on historical experience, we do not believe that there is significant risk that final premiums will differ substantially from those in the initial bid. We are soliciting comments on whether this timing may result in manipulation of bids and whether another measure of beneficiary costs, such as estimated OOPC, would be a more reliable measure to use given the difficulty of basing crosswalk approvals on final approved bids.

We recognize that some non-renewing plans may have very low premiums. A 100 percent increase for beneficiaries in a non-renewing plan with a current year premium of $14 would bring the following year's premium to only $28, which is less than 2022's base beneficiary premium of $33.37. We do not wish to prohibit plan crosswalk exceptions that would result in a large percentage increase and a relatively small dollar amount increase. Therefore, we propose to allow plan crosswalk exceptions where the premium increase would exceed 100 percent if the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), for the current year. We propose to use the current year's base beneficiary premium because the base beneficiary premium for the following year is not known at the time bids are submitted. CMS also does not wish to reveal an estimated base beneficiary premium before the official release of the date in late July.

We seek comment on alternatives to using the base beneficiary premium. Potential alternatives include a fixed

dollar amount, the low-income premium subsidy amount, described in § 423.780(b), for the non-renewing PBP's region, or the national average monthly bid amount, described in § 423.279.

The fourth and final proposed major modification to CMS's policy for consolidated renewal crosswalks at § 423.530(c)(1)(vii) is that sponsors that fail to request and receive a plan crosswalk exception would not be permitted to offer a new enhanced alternative PBP for the contract year after they non-renew an enhanced alternative PBP. For example, if a sponsor non-renews an enhanced alternative PBP effective 12/31/2023 and did not request and receive a plan crosswalk exception, we would decline to approve a new enhanced alternative PBP starting January 1, 2024. In other words, the earliest the sponsor would be permitted to create new PBP to replace the non-renewed PBP would be the 2025 plan year. We propose to adopt this restriction pursuant to the Secretary's authority at section 1857(e) of the Act, made applicable to the Part D program by section 1860D–12(b)(3) of the Act, to adopt additional terms and conditions as the Secretary may find necessary and appropriate. The proposed limitation on creating new PBPs would encourage sponsors to request plan crosswalk exceptions and discourage them from using the non-renewal process to disenroll beneficiaries who are high cost or who they otherwise no longer wish to serve. We believe this proposed policy will prevent discrimination and instability in the market. This policy is also consistent with other requirements in the Part D regulation, such as the restrictions at §§ 423.507(a)(3), 423.508(e), and 423.510(e)(1) on CMS entering into a new contract with sponsors that non-renewed or terminated a Part D contract for two years following the nonrenewal or termination.

These four proposed changes represent a significant shift from current policy. As such, we are soliciting comments on alternative approaches. Possible alternatives include, but are not limited to: (1) requiring plan crosswalks when a sponsor non-renews an enhanced alternative PBP while continuing to offer individual market coverage under the same PDP contract, but prohibiting sponsors from creating a new PBP to replace the non-renewing PBP; (2) adopting the requirements as proposed, but prohibiting sponsors from creating new PBPs to replace non-renewing PBPs even if a plan crosswalk exception is requested and received; (3) using an alternative measure, such as OOPC, instead of or in addition to plan premiums to assess whether a plan crosswalk exception should be granted; or (4) adopting the current subregulatory policy without modification.

We are also proposing requirements for contract consolidations that would reflect our current subregulatory policy, but with two significant differences that parallel the proposals with respect to consolidated renewals. For contract consolidations, consistent with our current policy, we propose at § 423.530(c)(2) to approve plan crosswalk exceptions from non-renewing PBPs into PBPs in the surviving contract when the surviving contract is held by the same sponsor or by a subsidiary of that sponsor's parent organization. We propose at § 423.530(c))(2)(i)–(iv) to adopt the following requirements of current subregulatory policy:

- The non-renewing PDP contract and the surviving contract must be held by the same legal entity or by legal entities with the same parent organization;
- The approved service area of the surviving contract must include the service area of the non-renewing PBPs whose enrollment will be crosswalked into the surviving contract;
- Enrollment may be crosswalked between PBPs offering the same type of prescription drug coverage (basic or enhanced alternative); and
- Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering basic prescription drug coverage.

The first significant change we propose to current subregulatory policy for contract consolidations is at § 423.530(c)(2)(v), which would require plan crosswalks from non-renewing PBPs offering enhanced alternative coverage into the PBP that would result in the lowest premium increase. Second, we propose at § 423.530(c)(2)(vi) to prohibit plan crosswalks that would result in a premium increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), compared to the current year premium for the non-renewing PBP. We are proposing these modifications to current contract consolidation crosswalk policy for the same reasons outlined with respect to consolidated renewal crosswalks. We acknowledge that contract consolidations are infrequent compared to consolidated renewals—as shown in Table 3, contract consolidation crosswalks occurred in only 2 of the last 5 years—and that data unique to contract consolidation crosswalks is therefore less available. However, we believe that requirements for the different types of plan crosswalk exceptions should be as consistent as possible and are therefore proposing to apply the same requirements with respect to premium increases for consolidated renewal crosswalks to contract consolidation crosswalks.

We solicit comments on these proposals.

6. Procedures for Requesting Plan Crosswalks (§ 423.530(d))

We propose to codify current procedures for submitting plan crosswalks and or making plan crosswalk exception requests at § 423.530(d), as described in ''Bid Pricing Tool for Medicare Advantage Plans and Prescription Drug Plans'' CMS–10142, posted for final comment pursuant to the Paperwork Reduction Act of 1995 at 87 FR 2441 (February 14, 2022). We propose that a Part D sponsor must submit all allowable plan crosswalks in writing through the bid submission process in HPMS by the bid submission deadline. Through the bid submission process, the Part D sponsor may indicate if a plan crosswalk exception is needed at that time; however, the Part D sponsor must also request a crosswalk exception through the crosswalk exception functionality in HPMS. CMS would verify the exception request and notify the requesting Part D sponsor of the approval or denial of the request after the plan crosswalk exception request deadline. CMS would approve any plan crosswalk exception that met the requirements of the proposed regulation. Because plan crosswalks are requested when a PBP is non-renewing, a denied crosswalk request would result in the PBP being non-renewed without enrollment being crosswalked. Part D sponsors would be required to submit these exception requests to ensure that PBP enrollment is allocated properly.

We solicit comments on this proposal.

7. Summary of Proposals

In summary, we are proposing to add a new § 423.530 codifying plan crosswalk requirements and policy for PDP contracts. We propose making the following changes:

- At proposed paragraph (a)(2)(i), prohibit plan crosswalks between PBPs under one PDP contract to PBPs under a different contract, unless the contracts are held by the same Part D sponsor or by sponsors that are subsidiaries of the same parent organization;
- At proposed paragraph (a)(2)(ii), prohibit plan crosswalks that split the

enrollment of one PBP into multiple PBPs;

- At proposed paragraph (a)(2)(iii), prohibit plan crosswalks between a PBP offering basic prescription drug coverage to a PBP offering enhanced alternative coverage;
- At proposed paragraph (b), require that renewing PBPs keep their enrollment and plan IDs from the previous year;
- At proposed paragraph (c), codify policy for plan crosswalk exceptions—including consolidated renewals and contract consolidations—with certain modifications relative to current subregulatory policy;
- At proposed paragraph (c)(1), permit consolidated renewal crosswalks when a sponsor non-renews an enhanced alternative PDP PBP while continuing to offer individual market coverage under the same PDP contract;
- At proposed paragraphs (c)(1)(iv) and (c)(2)(v), require that enrollment for enhanced alternative PBPs crosswalked pursuant to a crosswalk exception be crosswalked to the available PBP with the lowest premium increase;
- At proposed paragraphs (c)(1)(v) and (c)(2)(vi), prohibit plan crosswalks that would result in premium increase greater than 100 percent or higher than the base beneficiary premium for the current year, whichever is greater; and
- At proposed paragraph (c)(1)(vi), prohibit an organization that non-renews an enhanced alternative PBP without requesting and receiving a plan crosswalk exception from creating a new enhanced alternative PBP in the following contract year.
- At proposed paragraph (d), codify the process for requesting plan crosswalks for renewals and crosswalk exceptions.

We solicit comment on these proposals.

AE. Drug Management Program (DMP) Appeal Procedures (§ 423.562)

The Comprehensive Addiction and Recovery Act of 2016 (CARA) amended section 1860D–4(c)(5)(A) of the Act to provide that Part D plan sponsors may establish drug management programs (DMPs) for at-risk beneficiaries to reduce opioid overutilization in the Part D program. Subsequently, section 2004 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act provided that Part D plan sponsors must implement a DMP for plan years beginning on or after January 1, 2022.

We are proposing a technical change at § 423.562(a)(1)(v) that would remove discretionary language as it relates to a Part D plan sponsor's responsibility to establish a DMP under § 423.153(f) with appeal procedures that meet the requirements of subpart M for issues that involve at-risk determinations. This would eliminate the discretionary language and improve consistency with § 423.153(f), which requires each Part D plan sponsor to establish and maintain a drug management program and include appeal procedures that meet the requirements of subpart M for issues involving at-risk determinations. This provision would be strictly a technical change to the wording at § 423.562(a)(1)(v) and would not impact the underlying burden related to processing appeals of at-risk beneficiaries. Therefore, this proposal is not expected to have an economic impact beyond current operating expenses, and there is no paperwork burden or associated impact on the Medicare Trust Fund.

We solicit comments on this proposal.

AF. Part D Sponsor Website Requirements (§§ 423.2265(b)(12) and 423.2265(c)(1)(vi))

As required under §§ 422.111(h)(2), 422.2265, 423.128(d)(2), and 423.2265, all plans must have a website that includes specific posted materials and content. We are proposing two changes to the Part D sponsor website requirements at § 423.2265.

At paragraph § 423.2265(b)(12), we are proposing a technical correction to delete a duplicate reference to the prescription drug transition policy, as this information is already listed as required website content at § 423.2265(b)(10). We propose to remove the reference to the ''Prescription Drug Transition policy'' at paragraph (b)(12) and redesignate that paragraph as reserved.

We are also proposing to clarify the requirements at § 423.2265(c)(1)(vi) to be consistent with longstanding policy. Specifically, we wish to clarify that a Part D sponsor's utilization management criteria, as approved by CMS, must be posted on the plan's website by October 15 prior to the plan year. The regulation currently indicates that utilization management forms must be posted; however, we recognize that utilization management criteria themselves are distinct from the forms used to submit a coverage determination to satisfy said criteria. We understand that historically, Part D sponsors would post utilization management criteria within a customized coverage determination form for a particular drug. Part D sponsors still have the option of taking this approach; however, we have learned that in recent years, Part D sponsors have favored the approach of posting utilization management criteria without generating drug-specific utilization management forms. Specifically, Part D sponsors have used the CMS Part D Model Coverage Determination Request form referenced at § 423.2265(c)(2)(ii). This model form does not contain plan specific utilization management criteria. Plans may continue to take either approach—that is, posting plan-specific utilization management criteria within a custom form or separately from the model form. However, to account for the evolution in plan practice, we propose modifying paragraph § 423.2265(c)(1)(vi) to clarify the requirement that utilization management criteria (whether contained in a form or other format) must be posted on the plan's website by October 15 prior to the beginning of the plan year. By doing so, we ensure that beneficiaries can take the utilization criteria required to access a particular drug into account when evaluating their Part D plan options during the Annual Election Period (AEP). This revision also aligns the regulatory requirement with longstanding instructions from CMS in the ''Medicare Parts C and D Annual Calendar'' for Medicare Advantage (MA) plans, Medicare Advantage Prescription Drug (MA–PD) plans, and Prescription Drug Plans (PDPs) which specifies that Part D sponsors must post prior authorization and step therapy criteria on their websites by October 15 prior to the start of the benefit year.

We solicit comment on these proposals.

AG. Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors That Are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522)

In this proposed rule, we propose to amend 42 CFR part 422, subpart K, and part 423, subpart K, to codify in regulation our final settlement process for Medicare Advantage (MA) organizations and Part D sponsors whose contracts with CMS have been consolidated with another contract, non-renewed, or otherwise terminated.

Sections 1857(a) and 1860D–12(b)(1) of the Act require contracts between CMS and the legal entity that offers, respectively, one or more MA plans or Part D plans to beneficiaries. Sections 1857(e)(1) and 1860D–12(b)(3)(D)(i) of the Act provide that these contracts shall contain terms and conditions that the Secretary may find necessary and appropriate in addition to the applicable

requirements and standards set forth in the statute and the terms of payment set by the statute. At Part 422, subpart K, and Part 423, subpart K, we have codified provisions relating to the contracts between CMS and MA organizations and Part D sponsors, including a description of minimum terms that must be included in the contract; the duration of contracts; minimum enrollment, reporting, and prompt payment requirements; and provisions regarding the consolidation, nonrenewal, or termination of a contract. In addition, these contracts require compliance with the regulations governing the program, which are adopted as standards implementing and interpreting the statutory requirement and as new terms and conditions that are not inconsistent with, and necessary and appropriate for administration of, the MA and Part D programs. Our proposal here would add to those requirements.

CMS makes monthly payments to MA organizations and Part D sponsors for each beneficiary enrolled in a plan for that month. If there is an update to the payment amount that was paid for a month, CMS will make an adjustment to a month's payment for a beneficiary in a later month. For example, if beneficiary's Medicaid eligibility for a month is changed, CMS will recalculate the payment for that month after receipt of the updated Medicaid eligibility status for a beneficiary and make a retroactive payment update to that month's payment in a later month. In addition, CMS reconciles a number of different payment amounts after specified periods of time to permit plan data submission for a payment year as described below. These reconciliations typically take place the year after a payment year and result in retroactive payment adjustments for the prior payment year.

Generally, MA organizations and Part D sponsors continue to offer plans to beneficiaries from year to year. From time to time, a contract between CMS and an MA organization or Part D sponsor may consolidate, nonrenew, or otherwise terminate as a result of a plan initiated termination, mutual termination, or CMS initiated termination. Once a contract has consolidated, nonrenewed, or otherwise terminated, the retroactive payment adjustments for a year that would have been made had the contract remained in effect are not paid to the MA organization or Part D sponsor, but are held until after the reconciliations for the final payment year are calculated as described below. After such time, all retroactive adjustments to payment for the consolidated, nonrenewed, or otherwise terminated contract are totaled and either a net payment amount is made to the MA organization or Part D sponsor or an amount is charged to the MA organization or Part D sponsor.[173]

The process used to determine the final net payments for an MA organization or Part D sponsor, provide notice of these amounts to the MA organization or Part D sponsor, adjudicate disputes, and receive or remit payment constitutes the *final settlement process* and begins at least 18 months following the end of the last contract year in which the contract was in effect.

Before CMS determines the final settlement amount owed to or from an MA organization or Part D sponsor whose contract has consolidated, nonrenewed, or otherwise terminated, CMS first completes a series of reconciliation activities and calculates the related payment adjustments for both consolidated, nonrenewed, or otherwise terminated contracts as well as ongoing contracts: (1) MA risk adjustment reconciliation (described in § 422.310(g)), (2) Part D annual reconciliation (described in §§ 423.336 and 423.343), (3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320), and (4) medical loss ratio (MLR) report submission and remittance calculation (described in §§ 422.2460, 422.2470. 423.2460 and 423.2470). Each individual reconciliation process allows the MA organization or Part D sponsor to raise concerns about the calculation of that particular reconciliation amount. Once each reconciliation is complete and no errors have been identified, the MA organization or Part D sponsor is presumed to accept that reconciliation amount and it is not reconsidered during the final settlement process.

For a given consolidated, nonrenewed, or otherwise terminated contract, the *final settlement amount* is then calculated by summing the applicable reconciliation amounts from these 4 processes and any retroactive payment adjustments that accumulated after a contract has consolidated, nonrenewed, or otherwise terminated. Note that these reconciliation amounts represent all of the reconciliation amounts that could be included in the final settlement calculation. Whether each reconciliation amount will factor into the final settlement amount for a particular contract will depend on the specifics of that contract. For example, MA risk adjustment reconciliation would not be performed for a prescription drug plan contract.

The *final settlement adjustment period* is the period of time between when the contract consolidates, nonrenews, or otherwise terminates and the date the MA organization or Part D sponsor is issued a notice of the final settlement amount (also referred to herein as the *notice of final settlement*). The length of the final settlement period is determined by the time it takes for these reconciliations and related payment adjustments to be completed. During this time, CMS continues to calculate payment adjustments that reflect changes in beneficiary status.[174] CMS tracks all payment adjustments for a terminated contract for use in the final settlement for that contract.

The final settlement adjustment period ends on the date on the *notice of final settlement* that CMS issues to MA organizations and Part D sponsors. At the end of the final settlement adjustment period, CMS will no longer make adjustments to reconciliations for a contract that has consolidated, nonrenewed, or otherwise terminated, that would otherwise have been made for a continuing contract. Once the notice of final settlement has been issued, contracts that have been consolidated, nonrenewed, or otherwise terminated will also be excluded from all reopenings, including program-wide reopenings, or reconciliations for prior payment years when the contract was in effect. For example, under § 423.346, CMS has the authority to reopen and revise an initial or reconsidered Part D final payment determination, including the Part D reconciliation amounts included in the final settlement amount, for a prior payment year. However, this reopening would not apply to consolidated, nonrenewed, or otherwise terminated contracts that have already received a notice of final settlement. This allows CMS to largely close out any outstanding financial responsibilities associated with consolidated, nonrenewed, or otherwise terminated contracts, either on the part of CMS or on the part of the MA organization or Part D sponsor.[175]

[173] In the case of a bankrupt or liquidated plan that owes CMS money, CMS still completes the reconciliations, final settlement process, and issues a notice of final settlement, but refers the plan to the Department of Justice to collect the money owed.

[174] A beneficiary profile status change reflects a change in a beneficiary's economic or health status, such as low-income status for Part D, Medicaid status, Hospice or ESRD status.

[175] Once a contract has completed final settlement, the MA organization or Part D sponsor may still have financial responsibilities under section 1128J(d) of the Act.

After determining the final settlement amount, CMS issues a notice of final settlement to the MA organization or Part D sponsor for each contract that has consolidated, nonrenewed, or otherwise terminated, even if the final settlement amount is $0. The notice of final settlement explains whether the MA organization or Part D sponsor will receive or owe a final settlement amount and provides the information needed to conduct the associated financial transaction. The notice of final settlement includes the information CMS used to calculate the final settlement amount, including the payment adjustments that are reported on all monthly membership reports created from the date the contract ended until the month the final settlement amount was calculated. It also includes information on the process and timeline for requesting a review concerning the accuracy of the final settlement amount calculation.

We propose to codify longstanding and existing guidance pertaining to procedures for the final settlement process described in the above paragraphs. In addition, we propose to add a new appeals process for MA organizations or Part D sponsors that disagree with the final settlement amount. MAOs or Part D sponsors may request an appeal of the final settlement amount within 15 calendar days of the date of issuance of the notice of final settlement. We believe that will provide organizations with sufficient time to request an appeal, as MA organizations and Part D sponsors would already be aware of the reconciliation amounts that factor into the final settlement amount at the time the notice of final settlement is issued, and requiring a request for appeal within this timeframe would help ensure accurate and timely payment of final settlement amounts. If an MA organization or Part D sponsor agrees with the final settlement amount, no response would be necessary or required. Failure to request appeal within 15 calendar days of the date of issuance of the notice of final settlement would indicate acceptance of the final settlement amount. CMS would strongly encourage MA organizations and Part D sponsors to communicate their acceptance to CMS to facilitate prompt payment.

Finally, in addition to codifying our longstanding and existing review process under which MA organizations and Part D sponsors are able to request a reconsideration of CMS' final settlement amount calculation, we propose to add two additional levels of appeal: (1) an informal hearing conducted by the CMS Office of Hearings to review CMS' initial determination, following a request for appeal of the reconsideration of CMS' initial determination, and (2) a review by the CMS Administrator of the hearing officer's determination if there is an appeal of the hearing officer's determination. We believe that these additional levels of appeal will afford MA organizations and Part D sponsors sufficient opportunities to present objections to the calculation of the final settlement amount. This additional process would only be available to appeal CMS' final settlement amount calculation and would not be used to review any prior payments or reconciliation amounts. MA organizations and Part D sponsors seeking review of prior payments or reconciliation amounts must do so during the appropriate reconciliation process. CMS believes that these additional levels of appeal would only be used in exceptional circumstances given the narrow, mathematical nature of the final settlement process. We anticipate that calculation errors will be rare, and, if they do occur, that they will be quickly corrected to the mutual satisfaction of both parties without a need for further review.

1. Process for MA Organizations and Part D Sponsors That Do Not Request an Appeal

If an MA organization or Part D sponsor that owes a final settlement amount to CMS does not request an appeal or provides an optional response acknowledging and confirming the amount owed to CMS within 15 calendar days of the date of the notice of final settlement, the MA organization or Part D sponsor would be required to remit full payment to CMS within 120 calendar days of receiving the notice of final settlement. If an MA organization or Part D sponsor is owed money and does not appeal the final settlement amount, CMS would remit payment to the MA organization or Part D sponsor within 60 calendar days of the date of issuance of the notice of final settlement. If an MA organization or Part D sponsor does not owe or is not owed a final settlement amount and does not request an appeal of the $0 final settlement amount within 15 calendar days of the date of issuance of the notice of final settlement, no further actions would occur. If an MA organization or Part D sponsor does not appeal the final settlement amount indicated in the notice of final settlement within 15 calendar days of the issuance of the notice of final settlement no subsequent requests for appeal would be considered.

2. Process for Responses Requesting an Appeal of the Final Settlement Amount

In cases in which the MA organization or Part D sponsor submits a request for an appeal of the final settlement amount within 15 calendar days of the date of the notice of final settlement, the MA organization or Part D sponsor would have to specify the calculations with which they disagree and the reasons for their disagreement, as well as provide evidence supporting the assertion that CMS' calculation of the final settlement amount described in the notice of final settlement is incorrect. MA organizations and Part D sponsors would not be able to submit new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS would not consider information submitted for the purpose of retroactively adjusting a prior reconciliation.

CMS would not accept requests for appeal that are submitted more than 15 calendar days after the date of issuance of the notice of final settlement. As noted previously, if an MA organization or Part D sponsor does not reply within 15 calendar days, they would be deemed to accept the final settlement amount indicated in the notice of final settlement.

Once CMS has reconsidered the calculation of the final settlement amount in light of the evidence provided by the MA organization or Part D sponsor, CMS would provide written notice of the reconsideration decision to the MA organization or Part D sponsor.

If the MA organization or Part D sponsor does not agree with CMS's reconsideration decision, it would be able to request an informal hearing from a CMS hearing officer. The MA organization or Part D sponsor would have to submit a request for review within 15 calendar days of the date of CMS's reconsideration decision. The MA organization or Part D sponsor would be required to provide a copy of CMS' decision, the findings or issues with which it disagrees, and the reasons why it disagrees with CMS' decision. As the hearing officer's review would be limited to a review of the existing record, the MA organization or Part D sponsor would not be able to submit new evidence to support its assertion that CMS' calculation of the final settlement amount described in the notice of final settlement is incorrect in addition to the evidence submitted during CMS' reconsideration.

CMS would provide written notice of the time and place of the informal hearing at least 30 days before the

scheduled date and would provide a copy of the record that was before CMS when CMS made its reconsideration decision to the hearing officer. The CMS hearing officer would not receive new testimony or accept new evidence in addition to the evidence submitted by the MA organization or Part D sponsor during CMS' reconsideration to support its assertion that CMS' calculation of the final settlement amount is incorrect.

Once the hearing officer has reviewed the record, the hearing officer would send a written decision to the MA organization or Part D sponsor explaining the basis of the hearing officer's decision. The hearing officer's decision would be final and binding unless the decision is reversed or modified by the CMS Administrator.

If the MA organization or Part D sponsor does not agree with the hearing officer's decision, they would be able to request an additional, final review from the CMS Administrator. The MA organization or Part D sponsor would have to submit a request for review within 15 calendar days of the date of the issuance of CMS hearing officer's decision. The MA organization or Part D sponsor would be able to submit written arguments to the Administrator for review but would not be able to submit evidence in addition to the evidence submitted during CMS' reconsideration.

The CMS Administrator would have the discretion to elect to review the hearing officer's decision or decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision would be final and binding. If the Administrator elects to review the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor, the Administrator would review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor and determine whether to uphold, reverse, or modify the hearing officer's decision. The Administrator's decision would be final and binding and no other requests for review would be considered.

If an MA organization or Part D sponsor requests an appeal of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount will be stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the MA organization or Part D sponsor fails to request further review within the 15-day timeframe, CMS would communicate with the MA organization or Part D sponsor to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

At all levels of review, the MA organization or Part D sponsor's appeal would be limited to CMS' calculation of the final settlement amount. CMS would not consider information submitted for the purposes of retroactively adjusting a prior reconciliation. The MA organization or Part D sponsor would bear the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

We solicit comments on this proposal.

3. Proposed Amendments to Regulations (§§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522)

a. Definitions

We propose to amend §§ 422.500(b) and 423.501 to add several definitions relevant for the codification of the final settlement process.

First, we propose to add a definition for the term *final settlement amount,* which would be the final payment amount CMS calculates and ultimately pays to the MA organization or Part D sponsor or that an MA organization or Part D sponsor pays to CMS for a Medicare Advantage or Part D contract that has terminated through consolidation, non-renewal, or other termination. The proposed definition provides that CMS would calculate the final settlement amount by summing retroactive payment adjustments for a contract that accumulate after that contract consolidates non-renews, or otherwise terminates, but before the calculation of the final settlement amount, including the applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating the reconciliation amounts. These reconciliation amounts used in this process are: (1) MA risk adjustment reconciliation (described in § 422.310), (2) Part D annual reconciliation (described in §§ 423.336 and 423.343), (3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320), and (4) MLR report submission, including calculation of remittances (described in §§ 422.2470 and 423.2470).

We propose to add a definition for the term *final settlement process,* which we propose to define as the process by which CMS would calculate the final settlement amount for a Medicare Advantage or Part D contract that has been consolidated, nonrenewed, or otherwise terminated, issue the final settlement amount along with supporting documentation (described above) in the notice of final settlement to the MA organization or Part D sponsor, receive responses from MA organizations and Part D sponsors requesting an appeal of the final settlement amount, and take final actions to adjudicate an appeal (if requested) and make payments to or receive final payments from MA organizations or Part D sponsors. The proposed definition of *final settlement process* would specify that the final settlement process begins after all applicable reconciliations have been completed.

b. Final Settlement Process and Payment

We propose to add §§ 422.528 (for MA) and 423.521 (for Part D) to our regulations to codify our process for notifying MA organizations and Part D sponsors of the final settlement amount and how payments to or from CMS would be made.

Once CMS has calculated the final settlement amount, we would notify MA organizations and Part D sponsors of the final settlement amount. At paragraph (a) of proposed §§ 422.528 (for MA) and 423.521 (for Part D), we propose to codify that CMS would send a notice of final settlement to MA organizations and Part D sponsors. Specifically, proposed paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) specify that the notice would contain at least the following information: a final settlement amount; relevant banking and financial mailing instructions for MA organizations and Part D sponsors that owe CMS a final settlement amount; relevant CMS contact information; and a description of the steps for the MA organizations or Part D sponsor to request an appeal of the final settlement amount calculation.

CMS is seeking comment on the following proposals, which would change the current final settlement process. At paragraph (b) of proposed §§ 422.528 and 423.521, we propose to establish that MA organizations and Part D sponsors would have 15 calendar days from the date of issuance of the notice to request an appeal. We propose at paragraphs (b)(1) and (b)(2) of these new regulation sections that, if an MA organization or Part D sponsor agrees with the final settlement amount, no response would be required, and that, if an MA organization or Part D sponsor does not request an appeal within 15

calendar days, CMS would not consider any subsequent requests for appeal of the final settlement amount.

At proposed paragraph (c), we propose to codify the actions that would take place if an MA organization or Part D sponsor does not appeal the final settlement amount. Specifically, at paragraph (c)(1), we propose to specify that, if an MA organization or Part D sponsor owed a final settlement amount from CMS does not appeal, CMS would remit payment within 60 calendar days of the date of the issuance of the notice of final settlement. At proposed paragraph (c)(2), we propose that an MA organization or Part D sponsor that owes money to CMS and does not appeal would have to remit payment in full to CMS within 120 calendar days from issuance of the notice of final settlement. We further specify that an MA organization or Part D sponsor that does not appeal and does not remit payment within 120 calendar days of issuance of the notice would be subject to having any debts owed to CMS referred to the Department of Treasury for collection.[176]

At proposed paragraph (d), we propose to establish that the actions following submission of a request for an appeal would be taken per proposed §§ 422.529 (for MA) and 423.522 (for Part D).

At proposed paragraph (e), we propose that after the final settlement amount is calculated and the notice of final settlement is issued to the MA organization or Part D sponsor, CMS would no longer apply retroactive payment adjustments for the terminated contract and there would be no adjustments applied to the final settlement amount.

c. Requesting an Appeal of the Final Settlement Amount

We propose to add §§ 422.529 (for MA) and 423.522 (for Part D) to our regulations to codify that an MA organization or Part D sponsor would be able to request an appeal of the calculation of the final settlement amount, and the process and requirements for making such a request.

At paragraph (a) of proposed §§ 422.529 and 423.522, we propose to establish requirements that would apply to MA organizations' and Part D sponsors' requests for appeal of the final settlement amount calculation.

Specifically, at proposed paragraph (a)(1), we propose to establish the process under which an MA organization or Part D sponsor may request reconsideration of the final settlement amount. We propose to specify that the 15-calendar-day period for filing the request would begin on the date the notice of final settlement from CMS is issued. We also propose that MA organizations and Part D sponsors would have to include in their request the calculations with which they disagree and that the MA organization or Part D sponsor would have the obligation to provide evidence supporting the assertion that the CMS calculation of the final settlement amount is incorrect. We further specify that MA organizations and Part D sponsors should not submit new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS would not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

At proposed paragraph (a)(1)(iii), we propose to establish that the CMS reconsideration official would review the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the MA organization or Part D sponsor. We further propose to establish that the CMS reconsideration official would inform the MA organization or Part D sponsor of their decision on the reconsideration in writing and that their decision would be final and binding unless the MA organization or Part D sponsor requests a hearing officer review.

At proposed paragraph (a)(2), we propose to establish that MA organizations and Part D sponsors that disagree with CMS' reconsideration decision under paragraph (a)(1) of this section would be able to an informal hearing by a CMS hearing officer.

Specifically, at paragraph (a)(2)(i), we establish that MA organizations and Part D sponsors would have to submit their requests for an informal hearing within 15 calendar days of the date of the reconsideration decision. At paragraph (a)(2)(ii), we propose that MA organizations and Part D sponsors would have to include in their request a copy of CMS' decision, the specific findings or issues with which they disagree, and the reasons for which they disagree. At paragraph (a)(2)(iii), we propose to establish the informal hearing procedures. Specifically, we propose that CMS would provide written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date and would provide a copy of the record that was before CMS when CMS made its reconsideration decision to the hearing officer. We further propose that the hearing would be conducted by a hearing officer who would neither receive testimony nor accept new evidence. We finally propose that the hearing officer would be limited to the review of the record that was before CMS when CMS made its decision. At paragraph (a)(2)(iv), we propose that the CMS hearing officer would send a written decision to the MA organization or Part D sponsor explaining the basis for the decision. At proposed paragraph (a)(2)(v), we propose to establish that the hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator.

We further propose to establish at paragraph (a)(3) that MA organizations and Part D sponsors that disagree with the hearing officer's decision would be able to request a review by the CMS Administrator.

At paragraph (a)(3)(i), we establish that MA organizations and Part D sponsors would have to submit their requests for a review by the Administrator within 15 calendar days of the date of the decision and may submit written arguments to the Administrator for review. At paragraph (a)(3)(ii), we propose that the CMS Administrator would have the discretion to elect or decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. We further propose that if the Administrator declines to review the hearing officer's decision, the hearing officer's decision would be final and binding. We propose at paragraph (a)(3)(iii) that, if the Administrator elects to review the hearing officer's decision, the Administrator would review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written arguments submitted by the MA organization or Part D sponsor, and determine whether to uphold, reverse, or modify the decision. At proposed paragraph (a)(3)(iv), we propose that the Administrator's determination would be final and binding.

At proposed paragraph (b), we propose to establish the matters subject to appeal and that an MA organization or Part D sponsor bears the burden of proof. At proposed paragraph (b)(1), we propose to establish that the Part D sponsor's appeal would be limited to CMS' calculation of the final settlement amount. We further propose that CMS

[176] In the case of a bankrupt or liquidated plan that owes CMS money, CMS still completes the reconciliations and the final settlement process and issues a notice of final settlement, but refers the plan to the Department of Justice to collect the money owed.

would not consider information submitted for the purposes of retroactively adjusting a prior reconciliation. At proposed paragraph (b)(2), we propose that the MA organization or Part D sponsor would bear the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

At proposed paragraph (c), we propose that if an MA organization or Part D sponsor requests an appeal of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount would be stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the MA organization or Part D sponsor fails to request further review within the 15-calendar-day timeframe, CMS would communicate with the MA organization or Part D sponsor to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

Proposed paragraph (d) clarifies that nothing in this section would limit an MA organization or Part D sponsor's responsibility to comply with any other applicable statute or regulation, including section 1128J(d) of the Social Security Act.

We solicit comments on this proposal.

AH. Gross Covered Prescription Drug Costs (§ 423.308)

Section 1860D–15(b)(3) of the the Act defines ''gross covered prescription drug costs'' as, ''with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.'' In our final rule, ''Medicare Program; Medicare Prescription Drug Benefit,'' published in the **Federal Register** on January 28, 2005 (70 FR 4194), we codified the definition of ''gross covered prescription drug costs'' at § 423.308. This regulatory definition refers to ''gross covered prescription drug costs'' as ''actually paid costs.'' The term ''actually paid'' has a specific meaning in Medicare Part D and is separately defined at § 423.308 to mean costs actually incurred by the plan that are net of direct and indirect remuneration (DIR), including discounts, rebates, or other price concessions typically received and applied after the point of sale. However, unlike the statutory definitions of ''allowable reinsurance costs'' and ''allowable risk corridor costs'' at sections 1860D–15(b)(2) and 1860D–15(e)(1)(B) of the Act, respectively, the statutory definition of ''gross covered prescription drug costs'' at section 1860D–15(b)(3) of the Act does not use the phrase ''actually paid'' or otherwise specify that such costs must be net of all DIR. Because the definition of ''gross covered prescription drug costs'' was codified in regulation for the sole purpose of describing the methodology for calculating the reinsurance payment amount, in using the phrase ''actually paid'' in said regulatory definition of ''gross covered prescription drug costs,'' CMS was incorporating a requirement from the statutory definition of ''allowable reinsurance costs'' to emphasize that DIR would be netted out in the calculation of costs eligible for Part D reinsurance as required by the statute.

We note that certain provisions added to the Social Security Act by the Inflation Reduction Act of 2022 (IRA) refer to ''gross covered prescription drug costs as defined in section 1860D–15(b)(3) [of the Act]'' (see sections 1191(c)(5) and 1860D–14C(g)(4)(D) of the Act). Accordingly, we believe it is an appropriate time to revisit our regulatory definition of ''gross covered prescription drug costs'' to mirror the statute's language and to remove any ambiguity that might arise from the current regulatory definition as it may now also be applicable outside of the reinsurance context. Therefore, we propose to amend the definition of ''gross covered prescription drug costs'' at § 423.308 to remove the phrase ''actually paid.''

Revising the definition as proposed would not change the fact that Part D reinsurance is ultimately based on net drug costs or change the final reinsurance payment amount a Part D sponsor receives. Rather, as explained further below, allowable reinsurance costs would continue to be defined at § 423.308 as the subset of gross covered prescription drug costs actually paid. The proposed revision, therefore, would not constitute a change in policy or require a change in operations under Part D, and thus would not place any additional burden or reduce burden on Part D sponsors, nor result in government savings or costs.

1. Background

The term ''gross covered prescription drug costs'' (hereinafter referred to as ''GCPDC'') is defined and used at section 1860D–15(b) of the Act for the purpose of describing the methodology for calculating the reinsurance payment amount. As specified in section 1860D–15(b)(1)(A) of the Act, the reinsurance payment amount for a year preceding 2025 is equal to ''80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).'' As noted above, although the statutory definition of ''allowable reinsurance costs'' at paragraph (2) of section 1860D–15(b) of the Act specifies that such costs are the subset of GCPDC that are ''actually paid (net of discounts, chargebacks, and average percentage rebates),'' the statutory definition of GCPDC at paragraph (3) of that provision does not use the phrase ''actually paid'' or otherwise specify that such costs must be net of all DIR. This distinction, coupled with the use of the modifier ''gross'' to describe these costs indicates that the best reading of section 1860D–15(b)(3) of the Act is that GCPDC should reflect gross costs, not net costs that reflect all DIR that a Part D sponsor may receive. As stated above, CMS's use of the phrase ''actually paid'' in the current regulatory definition of GCPDC was intended to emphasize that all DIR would be netted out in the calculation of costs eligible for Part D reinsurance consistent with the plain language of the statute, which requires that the reinsurance payment amount be based on net drug costs. While the use of the phrase in the current regulatory definition of GCPDC is consistent with the statute for this reason, we recognize that that it may have led to ambiguity as to when the DIR would be netted out. We also recognize that the use of the phrase could create ambiguity when GCPDC is referenced outside of the reinsurance context (as it now is by the IRA).

It is important to note that the statutory definition of GCPDC further describes these costs as ''not including administrative costs, but including costs directly related to the dispensing of covered Part D drugs during the year and costs relating to the deductible.'' CMS has long held that costs directly related to the dispensing of covered Part D drugs are most logically calculated as the accumulated total of the negotiated prices that are used for purposes of determining payment to the pharmacy or other dispensing entity for covered Part D drugs, and which are required

under section 1860D–2(d)(1) of the Act to be made available to Part D beneficiaries and are used to adjudicate the Part D benefit (that is, used to determine plan, beneficiary, manufacturer, and government liability during the course of the payment year).[177] [178] As stated in several past rulemakings, we interpret the statutory definition of ''negotiated prices'' at section 1860D–2(d)(1)(B) of the Act as allowing the application of DIR at the point of sale, to reduce the negotiated price, either at the discretion of Part D plan sponsors or at the direction of CMS (see, for example, 70 FR 4244, 74 FR 1511, and 87 FR 27833). Therefore, even if the phrase ''actually paid'' were not included in the regulatory definition of GCPDC, GCPDC would continue to be reduced by POS DIR reflected in negotiated prices. However, such an accounting of POS DIR would not make the resulting amount ''actually paid,'' which requires the accounting for all DIR, including DIR not applied at the POS.

To mirror the statute's language and to remove any ambiguity that might arise from the current regulatory definition of GCPDC as described above, we propose to amend the definition of ''gross covered prescription drug costs'' at § 423.308 as discussed in greater detail below.

[177] This logic is borne out in the portion of our current regulatory definition of GCPDC at § 423.308 that states that GCPDC reflect ''actual costs.'' ''Actual cost'' is defined at § 423.100 as the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy.

[178] The different components of the negotiated price of a drug, and ultimately of GCPDC, are required to be reported separately using the following cost fields on the Prescription Drug Event (PDE) record submitted to CMS by Part D plan sponsors for payment purposes, the sum of which must equal GCPDC: Ingredient Cost, Dispensing Fee, Vaccination Administration, and Sales Tax. GCPDC are also required to be reported using the following two payment fields on the PDE record depending on whether the costs fall in the catastrophic phase: Gross Drug Cost Below the Out of Pocket (OOP) Threshold (GDCB) and Gross Drug Cost Above the OOP Threshold (GDCA). The amounts reported in these fields are then used to update the Total Gross Covered Drug Cost (TGCDC) Accumulator on the PDE record, which tracks and indicates which non-catastrophic phase of the Part D benefit the beneficiary is in. See, for example, 2006 Prescription Drug Event Data Training Participant Guide, available at *https://www.csscoperations.com/internet/csscw3_a.nsf/DIDC/K3V5B8PN1H~Prescription%20Drug%20Program%20(Part%20D)~Training,* and 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training.*

2. Proposed Change

Consistent with the language of section 1860D–15(b) of the Act, policy, including the current reporting requirements, and operations, including how the industry tracks and reports costs (that is, industry practice), we propose to amend the definition of ''gross covered prescription drug costs'' at § 423.308 to remove the two references to ''actually paid'' to clarify that GCPDC are not net of all DIR.

The proposed change would have no impact on Part D payment calculations or reporting requirements. Consistent with section 1860D–15(b)(2), the reinsurance payment amount would continue to be calculated based on drug costs net of DIR. Outside of the reinsurance context, CMS' long-standing operational guidance has instructed plans to report costs without first netting out DIR applied after the point of sale, and, thus, the guidance would not need to be adjusted as a result of this proposed change to the regulatory definition of GCPDC. For instance, the amounts reported in the Ingredient Cost, Dispensing Fee, Vaccine Administration, Sales Tax, GDCB, GDCA, and the TGCDC Accumulator fields on the PDE record are required to include costs incurred by the Part D sponsor and all amounts paid by or on behalf of an enrollee under a Part D plan.[179] Further, CMS guidance instructs Part D sponsors to net out only plan administrative costs and any DIR applied at the POS when reporting GCPDC.[180] Hence, a key step in calculating the Part D reinsurance payment amount is to determine the allowable reinsurance cost amount by subtracting from the GCPDC incurred in the catastrophic phase all DIR attributable to the proportion of catastrophic phase spending that was not already accounted for at the POS in order to determine the amount ''actually paid'' by the Part D plan and ensure that the reinsurance payment amount is ultimately calculated based on net drug costs. As we would continue to take this important step in determining allowable reinsurance costs for purposes of calculating the reinsurance payment amount even if ''actually paid'' were removed from the regulatory definition of GCPDC as proposed, there would be no change in the final reinsurance payment amount a Part D sponsor receives.

Moreover, no other rules or policies would be affected by this proposed change, including the rules regarding how to account for coverage not provided by the Part D sponsor, and instead provided by other payers, because they do not directly address the calculation of the reinsurance payment amount and thus do not rely on the current regulatory definition of GCPDC. For example, under rules regarding Medicare secondary payer (MSP) or subrogated claims, the amounts reported in the cost and payment fields of the PDE record reflect a reduction in the Part D plan's incurred cost for a drug resulting from other payer arrangements, which are currently and will continue to be captured in GCPDC.

We note that in a rulemaking published earlier this year, we amended our regulations at § 423.100, to add a new definition of ''negotiated price'' effective January 1, 2024. The new definition specifies, among other things, that the negotiated price for a Part D drug is the lowest possible reimbursement a network pharmacy will receive, in total, for the drug, net of all pharmacy price concessions. Thus, as of January 1, 2024, all price concessions from network pharmacies, negotiated by Part D sponsors and their contracted pharmacy benefit managers (PBMs), will be reflected in the negotiated price that is made available at the POS and reported to CMS on a PDE record, meaning that these pharmacy price concessions will be reflected in GCPDC even if the phrase ''actually paid'' is removed from the regulatory definition of the term as proposed. As noted above, accounting for DIR, including pharmacy price concessions, applied at the point of sale in the calculation of GCPDC, does not make the resulting amount ''actually paid,'' which requires accounting for all DIR, including DIR not applied at the POS.

While this proposed change to the regulatory definition would not be a change in policy and would not directly affect the way in which GCPDC are calculated and used for purposes of Part D, we believe it is important to revise the definition to remove any ambiguity regarding the meaning of the term ''gross covered prescription drug costs.'' As noted previously, the Inflation Reduction Act of 2022 added provisions

[179] See 2006 Prescription Drug Event Data Training Participant Guide, available at *https://www.csscoperations.com/internet/csscw3_a.nsf/DIDC/K3V5B8PN1H~Prescription%20Drug%20Program%20(Part%20D)~Training,* and 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training.*

[180] See page 1–15 of the 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training.*

to the Social Security Act that refer to ''gross covered prescription drug costs as defined in section 1860D–15(b)(3) [of the Act].'' Removing the phrase ''actually paid'' from the regulatory definition of GCPDC as proposed would eliminate any ambiguity in the regulation text and help to ensure there is a consistent understanding of the meaning of this term for purposes of both the Part D program and the relevant provisions of the IRA.

Nothing in this proposal places additional requirements on Part D sponsors or beneficiaries or changes how CMS currently uses the GCPDC reported by the Part D sponsor on the PDE for purposes of determining payments under Part D. This proposal is consistent with our current policy and operations, including the current reporting requirements. As such, the proposed change to the definition of ''gross covered prescription drug costs'' at § 423.308 would not place any additional burden on Part D sponsors, nor do we expect that this change would result in savings.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA)/Part C and Part D plans based on the requirement to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act and the collection of different types of quality data under section 1852(e) of the Act. The Part C and Part D Star Ratings system is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of beneficiary rebates under section 1854(b) of the Act. Cost plans under section 1876 of the Act are also included in the MA and Part D Star Ratings system, as codified at § 417.472(k). We use multiple data sources to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, information provided directly from health and drug plans, and data collected by CMS contractors. Various regulations, including §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156, require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans. The methodology for the Star Ratings system for the MA and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively, and we have specified the measures used in setting Star Ratings through rulemaking. In addition, the cost plan regulation at § 417.472(k) requires cost contracts to be subject to the Part 422 and 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System. (83 FR 16526–27). As a result, the proposals here would apply to the quality ratings for MA plans, cost plans, and Part D plans. We generally use ''Part C'' to refer to the quality measures and ratings system that applies to MA plan and cost plans.

We have continued to identify enhancements to the Star Ratings program to ensure it is aligned with the CMS Quality Strategy as that Strategy evolves over time. This includes clarifications as well as improvements related to the current methodology based on our recent experiences related to the impact of COVID–19 on quality measurement. The current CMS National Quality Strategy encourages the highest quality outcomes, safest care, equity, and accessibility for all individuals (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*). In addition to focusing on a person-centric approach as individuals move across the continuum of care, the current CMS Quality Strategy aims to create a more equitable, safe, and outcomes-based health care system and, where feasible, works to align performance metrics, programs, and policy across CMS programs.

In this proposed rule, we are proposing a health equity index reward to further incentivize Part C and D plans to focus on improving care for enrollees with social risk factors (SRFs), and this proposal supports CMS efforts to ensure attainment of the highest level of health for all people. We are also proposing to make changes in the specific measures used in the Star Ratings System:

- Remove the Part C Diabetes Care—Kidney Disease Monitoring measure;
- Remove the stand-alone Part C Medication Reconciliation Post-discharge measure;
- Add the updated Part C Colorectal Cancer Screening measure with the NCQA specification change;
- Add the updated Part C Care for Older Adults—Functional Status Assessment measures with the NCQA specification change;
- Add the updated Part D Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) measures (including non-substantive changes to the specifications).
- Add the Part C Kidney Health Evaluation for Patients with Diabetes measure;
- Add the Part D Concurrent Use of Opioids and Benzodiazepines measure;
- Add the Part D Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults measure; and
- Add the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measure.

We are also proposing to make several methodological changes:

- Reduce the weight of patient experience/complaints and access measures to further align the Part C and Part D Quality Rating System with other CMS quality programs;
- Remove guardrails when determining measure-specific-thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures;
- Modify the hold harmless policy for the Health Plan Quality Improvement and Drug Plan Quality Improvement measures;
- Add an additional basis for the subregulatory removal of Star Ratings measures; and
- Remove the 60 percent rule for the adjustment for extreme and uncontrollable circumstances (generally called the adjustment for disasters).

Finally, we are also proposing a series of technical clarifications of the existing rules related to adjustments for disasters, QBP appeals processes, contract consolidations, and weighting of measures with a substantive specification change, as well as a technical amendment to §§ 422.162(a)(2)(i) and 423.186(a)(2)(i) to fix a codification issue. Unless otherwise stated, proposed changes would apply (that is, data would be collected and performance measured) for the 2024 measurement period and the 2026 Star Ratings.

Section VIII includes simulations of the cumulative impact of these proposals on overall Star Ratings using data from the 2021 Star Ratings, including simulations by contract size and by geographical area—specifically, by State, DC, and Puerto Rico.

B. Definitions (§§ 422.162 and 423.182)

We propose to add the following definition for Part 422, Subpart D (for Part C plans) and Part 423, Subpart D (for Part D plans) in paragraph (a) of §§ 422.162 and 423.182, respectively. This proposed new definition is relevant for our proposed policies

discussed in section V.G. of this proposed rule and would be used in that context.

- Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

C. Contract Ratings (§§ 422.162(b) and 423.182(b))

1. Contract Type

In the April 2018 final rule (83 FR 16440) at §§ 422.162(b) and 423.182(b), we codified the methodology for calculating the same overall and summary Star Ratings for all plan benefit packages (PBPs) offered under each MA-only, MA–PD, or PDP contract.

As different organization or contract types offer different benefits, the overall and summary Star Ratings differ across contract types when the set of required measures differs. For example, non-SNP contracts do not submit the following measures and, therefore, their overall and Part C summary ratings do not include them: SNP Care Management, Care for Older Adults—Medication Review, and Care for Older Adults—Pain Assessment.

We propose to amend §§ 422.162(b)(1) and 423.182(b)(1) to add a sentence at the end to clarify that the overall and summary Star Ratings are calculated based on the measures required to be collected and reported for the contract type being offered for the Star Ratings year. This is our current practice and how the Star Ratings have historically been calculated. For example, the 2023 Star Ratings are calculated for the 2023 contract year using data primarily from measurement year 2021.[181] The 2023 Star Ratings are published on Medicare Plan Finder in October 2022 to provide comparative quality performance information about plans for people with Medicare to use in making enrollment decisions for the 2023 calendar year. If a contract offered a SNP PBP in measurement year 2021, but is no longer offering a SNP PBP for the 2023 contract year, the 2023 Star Ratings exclude the SNP-only measures and the contract would be rated as ''Coordinated Care Plan without SNP''. This is our current (and historical) process and how the proposed regulatory clarification will be applied. We welcome comments on this proposal.

2. Contract Consolidations

The process for calculating measure scores for contracts that consolidate is specified as a series of steps at §§ 422.162(b)(3) and 423.182(b)(3). As described in the April 2018 final rule (83 FR 16528 through 16531), we use the enrollment-weighted means of the measure scores of the consumed and surviving contract(s) to calculate the measure-level ratings for the first and second years following the contract consolidation. For all contracts, under §§ 422.164(f)(4) and 423.184(f)(4), the Part C and Part D improvement measures compare current contract-level measure scores with scores from the prior year across all measures included in the improvement measures calculations. Given there are no comparable prior year measure-level scores available for contracts in the first year of the consolidation, historically we have not calculated the Part C and D improvement measures for the first year after a consolidation.

We propose to amend §§ 422.162(b)(3)(iv)(A)(*1*) and 423.182(b)(3)(ii)(A)(*1*) to clarify the calculation of the Part C and Part D improvement measures for contracts that consolidate. For the first year after a consolidation, we propose to clarify that the Part C and Part D improvement measures will not be calculated for the consolidated contract. The prior year measure-level scores only include data from the surviving contract; using those as the comparison point for a consolidated contract would not be an accurate comparison because it does not include any information about performance of the consumed contract(s). For the second year after a consolidation, the improvement measure is calculated, using the enrollment-weighted measure scores for the current and prior year because scores for both years are available for the consolidated contract. This is our current (and historical) process and how the proposed regulatory clarification will be applied.

We propose to revise the current regulation text at §§ 422.162(b)(3)(iv)(A)(*1*) and 423.182(b)(3)(ii)(A)(*1*) to clarify that the Part C and Part D improvement measures are not calculated for the first year after a contract consolidation. This proposal codifies our current application of the ratings rules. We welcome comments on this proposal.

D. Adding, Updating, and Removing Measures (§§ 422.164 and 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. In the April 2018 final rule, at 83 FR 16532, we stated we are committed to continuing to improve the Part C and Part D Star Ratings system and anticipated that over time measures would be added, updated, and removed. We also specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. The regulations, at paragraph (d)(1), list examples of non-substantive updates. See also 83 FR 16534–37. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and their specifications) adopted for the Part C and Part D Star Ratings program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance issued 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, 2024 unless noted otherwise. We are also proposing a new rule for the removal of measures and an additional example of a non-substantive measure update.

1. Proposed Measure Removal

a. Diabetes Care—Kidney Disease Monitoring (Part C)

We are proposing to remove the Diabetes Care—Kidney Disease Monitoring measure because it has been retired by the measure steward.[182] NCQA, the measure steward, announced the retirement of the Diabetes Care—Kidney Disease Monitoring measure after measurement year 2021. As we stated in the Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, since NCQA will no longer be collecting data for this Healthcare Effectiveness Data and Information Set (HEDIS) measure beginning with measurement year 2022, CMS will not have data for this measure to be included in the 2024 Star Ratings. The measure will be included in the

[181] There are exceptions to this for some measures. For example, as adopted in the April 2018 final rule and used now, the measures from the CAHPS survey are based on the most recent data submitted from surveys of enrollees; the surveys ask about the experience of the enrollees over the last six months. The annual Medicare Part C & D Star Ratings Technical Notes (available online here: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData*) identify the measures and their data sources for each year's Star Ratings.

[182] The measure, which has the HEDIS label ''Comprehensive Diabetes Care (CDC)—Medical Attention for Nephropathy'' was retired after the 2021 performance period as noted here *https://www.ncqa.org/wp-content/uploads/2022/07/Summary-Table-of-Changes-HEDIS-MY-2022.pdf* and does not appear in the list for the 2022 performance period.

2023 Star Ratings using data from measurement year 2021. We are proposing to replace this measure with the Kidney Health Evaluation for Patients with Diabetes measure (described in section V.D.3.a. of the preamble to this proposed rule).

CMS is proposing to permanently remove the Diabetes Care—Kidney Disease Monitoring measure starting with the 2024 Star Ratings because we will not have data to calculate the measure.

b. Medication Reconciliation Post-Discharge (Part C)

We are proposing to remove the Medication Reconciliation Post-Discharge (MRP) measure as it would be duplicative of the MRP component of the Transitions of Care (TRC) measure to be included in the 2024 Star Ratings. In the January 2021 final rule at 86 FR 5921–24, CMS finalized inclusion of the TRC measure in the 2024 Star Ratings. The TRC measure includes four indicators: MRP, Notification of Inpatient Admission, Patient Engagement After Inpatient Discharge, and Receipt of Discharge Information. Currently, MRP appears in both the Medicare Part C and Part D Star Ratings as a stand-alone measure and on the Medicare Part C and D display page as one of the four indicators included in the TRC measure. As discussed at 86 FR 5921 through 5924, transitions from an inpatient stay back to home often result in poor care coordination, including communication gaps between inpatient and outpatient providers; planned and inadvertent medication changes; incomplete diagnostic work-ups; and insufficient understanding of diagnoses, medication, and follow-up care needs. The Merit-based Incentive Payment System (MIPS) also includes MRP [183] which is one component of the TRC measure. Although at this time CMS is only implementing the TRC measure in the Part C Star Ratings program, it is a HEDIS measure and over time, it may be used in other programs. Based on the importance of care coordination in the Part C program and how the TRC measure provides a more comprehensive picture of how plans manage transitions across settings for care, we believe its inclusion in the Part C Star Ratings is appropriate.

For measurement year 2020, NCQA provided multiple updates to the TRC measure as described at 86 FR 5921 and 5922. In one of these updates, NCQA revised the requirement of using one medical record from a specific provider to, instead, allow numerator information to be captured from additional communication forms accessible to the primary care provider or ongoing care provider (for example, admissions, discharges, and transfers (ADT) feeds, shared electronic medical records (EMRs)) that occur regularly in the field and meet the intent of the measure. This change also ensured that scores for the MRP indicator in the TRC measure and the stand-alone MRP measure would match. Currently, the MRP measure for the Part C and Part D Star Ratings comes from the MRP indicator collected through the TRC measure. This is because NCQA decided that the stand-alone MRP measure no longer needed to be separately reported since it could be pulled from the medication reconciliation indicator in the TRC measure.

CMS is proposing to remove the stand-alone MRP measure from the 2026 Star Ratings for measurement year 2024 since the same information about medication reconciliation is now also incorporated as a component of the TRC measure and, consequently, it is duplicative to have MRP as a stand-alone measure and as a component of the TRC measure. We welcome comments on this proposal.

2. Proposed Measure Updates

In the April 2018 final rule, we specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. (83 FR 16534 and 16535). Where an update by the measure steward is substantive within the scope of §§ 422.164(d)(2) and 423.184(d)(2), CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then engage in rulemaking to make substantive changes to a Star Ratings measure. Per §§ 422.164(d)(2) and 423.184(d)(2), CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings. This 2 year period for the updated measure to be on the display page may overlap with the period during which CMS solicits comment and engages in rulemaking. Further, the legacy measure may continue to be used in the Star Ratings during this period.

a. Colorectal Cancer Screening (Part C)—Substantive Change

CMS is proposing a substantive update to the existing colorectal cancer screening measure because of changes in the applicable clinical guidance and by the measure steward. In May 2021, the U.S. Preventive Services Task Force (USPSTF) released updated guidance for the age at which colorectal cancer screenings should begin. Subsequently, NCQA, the measure steward, has updated its colorectal cancer screening measure to include a rate for adults 45–49 years of age for measurement year 2022. Therefore, CMS proposes expanding the age range for the Colorectal Cancer Screening measure to adults age 45–49, for an updated age range of 45–75, for the 2024 and subsequent measurement years. The expanded age range for this screening measure significantly increases the size of the population covered by this measure and is therefore a substantive measure specification change within the scope of § 422.164(d)(2). Other CMS programs, such as for the qualified health plans (QHPs) [184] and the adult core set for Medicaid plans,[185] are planning to introduce this change into their programs as they also use the same HEDIS measure.

CMS solicited feedback on making this substantive update to the measure in the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, and most commenters supported this change. As described in the April 2018 final rule (83 FR 16534), we may keep a legacy measure in the Star Ratings during the period that an updated version of the measure is on the display page. The legacy measure with the narrower age range of 50–75 years will remain available and be used in Star Ratings until the updated measure has been adopted through rulemaking and has been on the display page for 2 years. The updated measure will be on the display page for the 2024 Star Ratings, starting with the 2022 measurement year data.

b. Care for Older Adults—Functional Status Assessment (Part C)—Substantive Change

We are proposing to add the Care for Older Adults (COA)—Functional Status

[183] Quality ID #46 (NQF 0097): Medication Reconciliation Post-Discharge—National Quality Strategy Domain: Communication and Care Coordination—Claims (*cms.gov*).

[184] *https://www.cms.gov/files/document/final-2022-call-letter-qrs-qhp-enrollee-survey.pdf.*

[185] *https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html.*

Assessment measure back to the Star Ratings after it has been on the display page following a substantive measure specification change. The COA measure is collected for Special Needs Plans (SNPs) and includes three indicators—Medication Review, Functional Status Assessment, and Pain Assessment.

For HEDIS 2021, based on the 2020 measurement year, NCQA implemented a change for the COA—Functional Status Assessment. Previously the measure specification was that documentation of a complete functional status assessment must include: (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were assessed; (3) result of assessment using a standardized functional assessment tool; or (4) notation that at least three of the following four components were assessed: (a) cognitive status, (b) ambulation status, (c) hearing, vision, and speech (that is, sensory ability), (d) other functional independence (for example, exercise, ability to perform job). Because the clinical field of functional status assessment was moving toward agreement on assessment using ADLs, IADLs, or another standardized tool, and to improve the clarity of the specification, NCQA removed the fourth option for meeting the numerator requirements for this indicator for HEDIS 2021.

The measure change for the COA—Functional Status Assessment measure was considered substantive under § 422.164(d)(2) because removal of a mechanism for positive performance on the measure may meaningfully impact the numerator. The updated measure was moved to the display page starting with the 2022 Star Ratings.

CMS is proposing to return this updated measure to the Star Ratings, beginning with the 2026 Star Ratings and 2024 measurement period. With the updated specification, documentation of a complete functional status assessment must include: (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were assessed; or (3) result of assessment using a standardized functional assessment tool. For weighting purposes, a substantively updated measure is treated as a new measure, and as described at § 422.166(e)(2), will receive a weight of 1 for the first year in the Star Ratings; this treatment of substantively updated measures as new measures for purposes of weighting was addressed in the January 2021 final rule (86 FR 5919) and is proposed to be more clearly addressed in § 422.166(e)(2) in section V.E.2 of this proposed rule. Therefore, this measure will receive a weight of 1 for its first year and will be treated as a process measure in subsequent years.

c. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D)—Substantive Change

CMS proposes to implement risk adjustment (also sometimes referred to as case-mix adjustment) based on sociodemographic status (SDS) characteristics, a substantive update, to the three Part D medication adherence measures for the 2028 Star Ratings (2026 measurement year). Health outcomes are affected by patient-related and external factors such as existing clinical conditions and SDS. Currently, the medication adherence measures (Diabetes, Hypertension, and Cholesterol) are included in the determination of the Star Ratings Categorical Adjustment Index (CAI) because they are not excluded by the criteria established in §§ 422.166(f)(2) and 423.186(f)(2); for example, the measures are not case-mix adjusted for socioeconomic status. The CAI was implemented in the 2017 Star Ratings to adjust for average within-contract disparity in performance associated with the percentages of beneficiaries who receive low income subsidy and/or dual eligible (LIS/DE) and/or have disability status. The CAI was initially developed as an interim analytical adjustment to address concerns about disparities while longer-term solutions were explored, including engaging with measure stewards to examine if re-specification is warranted for measures used in the Star Ratings. The methodology for the CAI was codified at §§ 422.166(f)(2) and 423.186(f)(2); the factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part D for MA–PDs, and Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

In addition, the National Quality Forum (NQF) convened an expert panel in 2014 and recommended that performance-based measures should be risk adjusted for socioeconomic status (SES) and other socio demographic factors in 2017. On June 28, 2020, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) submitted a second Report to Congress; [186] ASPE is required under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) to study the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use in Medicare value-based purchasing programs.

CMS contracted with the Pharmacy Quality Alliance (PQA), the steward of these measures, to examine the medication adherence measures for potential risk adjustment. PQA recommended sociodemographic status (SDS) risk adjustment for the Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures. PQA recommended and endorsed the following changes related to SDS in their Measure Manual:

- All three adherence measures should be risk adjusted for SDS characteristics to adequately reflect differences in patient populations.
- The measures should be adjusted for the following beneficiary-level SDS characteristics: age, gender, dual eligibility/low-income subsidy (LIS) status, and disability status.
- The measures should be stratified by these four beneficiary-level SDS characteristics (listed in the prior bullet) to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The PQA measure specifications were endorsed by NQF in the 2019 Spring cycle (NQF endorsed #0541).

CMS has included stratifications by age, gender, dual eligibility/LIS status, and disability status in the Medication Adherence patient safety reports to Part D sponsors beginning with the 2019 measurement year.

We are proposing to implement risk adjustment for the medication adherence measures based on the PQA specifications, which would be reflected in the Star Ratings. Additionally, because the medication adherence measures will be risk adjusted based on SDS characteristics (that is, for age, gender, dual eligibility/LIS, and disability status), the medication adherence measures will be excluded from the CAI adjustment per §§ 422.166(f)(2)(ii)(A) and 423.186(f)(2)(ii)(A). We found in our analysis that implementing the SDS risk adjustment to the patient safety reports can be very time consuming and should be incorporated at one period of time. Therefore, since we are proposing to implement the SDS risk adjustment to the medication adherence measures and remove these measures from the Star Ratings CAI determination, we also

[186] *https://www.aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

intend to incorporate the SDS risk adjustment operationally to the medication adherence measures reported by CMS to Part D sponsors in the last monthly patient safety report for the measurement year.

In developing this proposal, we considered how this change might affect Star Ratings for MA–PD and PDP contracts. We calculated SDS risk adjusted medication adherence measure rates using year of service (YOS) 2019 measurement year data and recalculated the CAI values excluding these three adherence measures. We then recalculated the overall and Part D summary ratings using the SDS risk adjusted medication adherence measure rates, revised CAI values, the final 2021 Star Ratings for other measures, and the reward factor. In our analysis, we found that the threshold shifts for measure-level cut points with SDS risk adjustment were minimal for both MA–PD and PDP contracts, ranging from –2 to +1 percentage point(s) for MA–PD contracts and about –2 to +3 percentage points for PDP contracts. We found that for both MA–PD and PDP contracts, approximately 60–70 percent of contracts retained the same star level across the Medication Adherence for Hypertension (RAS Antagonists) and Medication Adherence for Cholesterol (Statins) measures. When a star level shift was observed, most of the MA–PD and PDP contracts shifted by one-star level and usually shifted upwards when the SDS risk adjustment was applied to the adherence measures. One percent of MA–PD contracts shifted two-star levels for the Medication Adherence for Hypertension (RAS Antagonists) and Medication Adherence for Cholesterol (Stains) measures. The two-star level shifts were primarily upwards, but one contract did shift down two stars in the Medication Adherence for Cholesterol (Stains) measure. For the Medication Adherence for Diabetes Medication measure, 82 percent of MA–PD contracts and 59 percent of PDP contracts retained the same star level. When a star level shift was observed for the Medication Adherence for Diabetes Medications measure, most MA–PD and PDP contracts saw a one-star downward movement with the SDS risk adjustment applied to the measure.

As previously noted, if CMS implements SDS risk adjustment for the three medication adherence measures, the measures would no longer be included in determining the Star Ratings CAI. Therefore, we also conducted an analysis to simulate calculating the CAI values without case-mix adjusting the three adherence measures for LIS/DE and disability; these simulated CAI values were used in the application of the simulated summary rating calculations. For most MA–PD contracts, this resulted in a negative shift in the CAI adjustment values for the overall and Part D summary ratings, and in contrast, most PDPs had a positive shift in values. Additionally, the analysis found a minimal change in reward factor thresholds, ranging from –0.07 to +0.02 for mean percentile thresholds and –0.08 to +0.008 for variance percentile thresholds. In the analysis of the overall and Part D summary rating, 91 percent of MA–PD contracts retained the same overall rating, 7 percent decreased by half a star, and 2 percent increased by half a star. We found that 81 percent of MA–PD contracts retained the same Part D summary rating, 11 percent decreased by half a star, and 7 percent increased by half a star. The impact on PDP contracts was neutral or positive; 63 percent of PDP contracts retained the same Part D summary rating star level while 37 percent increased by a half a star. No PDP contracts had a decrease in their Part D summary rating.

The Part C and Part D improvement measures were not recalculated for this simulation. The final 2021 Star Ratings for both improvement measures were used for the summary rating recalculations in the simulations to illustrate the impact of this proposed change to the three medication adherence measures. Additionally, the final 2020 Star Ratings for both improvement measures and for the three adherence measures were used for the CAI value recalculations in the simulations. It is possible that the simulated differences could vary if or when we are able to have two consecutive years of adjusted data for recalculating these components.

Per § 423.184(d)(2), the change to implement SDS risk adjustment for the three Part D medication adherence measures would be a substantive update. We signaled this potential update and solicited initial feedback on incorporating the SDS risk adjustment in the Advance Notice and Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. A majority of the commenters supported SDS risk adjustment for the medication adherence measures. Some commenters also requested information on how the CAI will be affected by this update. We completed testing of the impact of the adjustment and are including the additional information about the simulations in this proposed rule, as summarized previously. If finalized, the legacy medication adherence measures would remain in the Star Ratings and the updated medication adherence measures with the SDS risk adjustment would be on the display page for at least 2 years (beginning with the 2024 measurement year for the 2026 display page). Beginning with the 2026 measurement year and 2028 Star Ratings, CMS would then move the re-specified measures from display page to Star Ratings and the legacy measures would be removed under this proposal. We solicit comments on this substantive update to incorporate SDS risk adjustment for the medication adherence measures.

d. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D)—Non-Substantive Changes

In addition to the substantive changes (to add risk adjustment for SDS for the three adherence measures), our analysis of the proposed substantive updates incorporated two non-substantive changes to the adherence measures, based on the current PQA measure specifications, which are endorsed by NQF. While we do not need to propose non-substantive changes through rule-making, given that we intend to make the non-substantive changes to the measures along with the proposed substantive changes to risk adjust the adherence measure, we describe the non-substantive updates as well in this preamble in order to provide a full picture of the changes to these measures. However, implementing these non-substantive updates is not dependent on finalizing the SDS risk adjustment proposal and will be included in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. These specification changes are non-substantive in accordance with § 423.184(d)(1) because they narrow the denominator population or do not change the target population or intent of the measure: (1) apply continuous enrollment (CE) instead of member-years (MYs) adjustment and (2) no longer adjust for stays in inpatient (IP) settings and skilled nursing facilities (SNFs).

Currently, the Part D enrollment used by CMS in the medication adherence measures is adjusted monthly based on MYs to account for beneficiaries who are enrolled for only part of the contract year enrollment (for example, if a beneficiary is enrolled in the Part D contract for 6 out of 12 months of the

year, the beneficiary will count only as 0.5 member-years in the rate calculation). Moving forward when applying the SDS risk adjustment for the medication adherence measures, CMS intends to discontinue the use of MY of enrollment, which is a non-substantive update. Rather, we intend to align with PQA measure specifications of CE as defined by the treatment period and exclude beneficiaries with more than 1-day gap in enrollment during the treatment period.

According to the current PQA measure specifications, the treatment period begins on the earliest date of service for a target medication during the measurement year which is the index prescription start date (IPSD) and extends through whichever comes first: the last day of the enrollment during the measurement year, death, or end of the measurement year. The treatment period should be at least 91 days. Therefore, a beneficiary may meet the requirements of enrollment in more than one contract in a measurement year but partial enrollment during the measurement year will no longer be adjusted using MYs methodology; this beneficiary may be eligible to be included in the measure calculation if continuously enrolled in one contract even if the beneficiary disenrolls from the contract prior to the end of the measurement year and enrolls into a different contract based on the PQA definition of CE. To clarify, per the current PQA measure specifications of treatment period, beneficiaries can have only one treatment period per contract—meaning if a beneficiary disenrolls after the IPSD and then re-enrolls (in the same Part D plan) in the same contract during the same measurement year, the beneficiary would not be included in the measure calculation for that particular contract if there is more than a one day gap in enrollment during the treatment period. If a beneficiary is enrolled in a Part D plan offered under one contract but then disenrolls and enrolls into a Part D plan offered under another (that is, different) contract and subsequently the beneficiary meets the measure criteria for one or both contracts, the beneficiary will be included in the measure rate calculation for all the applicable contract(s). The beneficiary partial enrollment would no longer be adjusted for partial MY enrollment (for example, 0.5) which accounts for a fraction of the beneficiary's enrollment in a contract but would now be calculated as 1 for rate calculation purposes under the CE methodology. CMS conducted an analysis of beneficiaries who met CE in the same contract using the YOS 2019 Patient Safety reports. Approximately 95 percent of beneficiaries met the definition for being continuously enrolled for the Medication Adherence for Diabetes Medications measure and about 96 percent for the Medication Adherence for Hypertension Medications (RAS Antagonists) and Medication Adherence for Cholesterol Medications (Statins) measures.

Using YOS 2019 data, CMS analyzed the impact of implementing both the proposed SDS risk adjustment and the use of the current PQA measure specification definition of CE (instead of MY) for the three medication adherence measures. The analysis was limited to Part D contracts that were included in the 2021 Star Ratings for comparison purposes. Based on our analysis, we found that most MA–PD contract measure rates remained the same after the SDS risk adjustment and CE updates were applied. The change in distribution of rates among MA–PDs was negligible (at most 1 percentage point difference on average) between the current MY methodology and the SDS risk adjustment with CE methodology for all three medication adherence measures. Similarly, for PDPs, the change in distribution of rates among PDPs was minimal (at most 1 to 2 percentage point difference on average).

Currently, we also adjust for Part D beneficiaries' stays in IP settings and SNFs. However, CMS plans to make a non-substantive change to discontinue adjusting for SNF and IP stays in calculating these measures. Our overall goal in making these non-substantive changes to the adherence measures is to fully align with current PQA measure specifications endorsed by the NQF; the PQA specifications do not include IP/SNF stay adjustments in the adherence measures. In addition, during our testing of both this adjustment and the SDS risk adjustment, we found that applying IP and SNF stay adjustments added a level of complexity and concerns about the accuracy of the SDS risk adjustment.

In our analysis of comparing SDS adjusted rates with and without IP/SNF stays, the impact of the IP/SNF stay adjustment had very minimal impact to the distribution of measure rates for all three adherence measures for MA–PDs and PDPs. For the Medication Adherence for Diabetes measure, the mean rates remained the same for both MA–PDs (85 percent) and PDPs (84 percent) regardless of whether the IP/SNF stay adjustment was included or not. Similarly, for the Medication Adherence for Hypertension (RAS antagonists) measure, the mean rates for the MA–PDs remained the same at 86 percent regardless of IP/SNF stay adjustment, and for PDP contracts, there was a 1 percentage point difference seen in the mean rates between the two methods (86 percent with IP/SNF stay adjustment and 85 percent without IP/SNF adjustment). Likewise, for the Medication Adherence for Cholesterol (Statin) measure, there was a 1 percentage point difference in the mean rates for the MA–PDs (85 percent with IP/SNF stay adjustment and 84 percent without IP/SNF adjustment), and the mean rates remained the same for PDPs (84 percent) regardless of whether IP/SNF stay adjustment was included or not.

We plan to implement CE starting with the 2024 measurement year for the 2026 Star Ratings. We plan to remove the IP/SNF stay adjustment from the adherence measures starting with the 2026 measurement year for the 2028 Star Ratings, which is the same time we propose to implement the SDS risk adjustment change, but is not dependent on finalizing that proposal.

3. Proposed Measure Additions

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on improving clinical and other health outcomes. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. 83 FR 16521, 16533. For example, we regularly review measures developed by NCQA and PQA. CMS is proposing to adopt the new measures described in this rule, which are measures developed by NCQA or PQA. The Kidney Health Evaluation for Patients with Diabetes measure has been collected since 2020 measurement year and the new Part D measures are calculated from prescription drug event or CMS administrative data so they do not require any new data collections.

a. Kidney Health Evaluation for Patients With Diabetes (Part C)

We propose to add the Kidney Health Evaluation for Patients with Diabetes (KED) measure to the 2026 Star Ratings. This measure was introduced as a HEDIS measure for the 2020 measurement year. NCQA, in collaboration with the National Kidney Foundation, developed a kidney health evaluation measure, and NCQA tailored the measure specifically for health plans. The KED NCQA measure assesses whether adults who have diabetes received an annual kidney profile evaluation, defined by an estimated

Glomerular Filtration Rate (eGFR) [187] and a Urine Albumin-Creatinine Ratio (UACR) during the measurement year. This new measure aligns with recommendations from the American Diabetes Association and provides critical information for screening and monitoring of kidney health for patients with diabetes. This measure would replace the prior related measure, Diabetes Care—Kidney Disease Monitoring.

CMS began reporting this measure on the display page for the 2022 Star Ratings. As provided at §§ 422.164 (c)(3) and (4) and 423.184(c)(3) and (4) (83 FR 16534), as new performance measures are developed and adopted they are initially posted on the display page for at least 2 years.

We have submitted the KED plan measure through the 2022 Measures Under Consideration process for review by the Measures Application Partnership, which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs. The MIPS program has also submitted it to the 2021 Measures Under Consideration process and this measure will also be implemented for QHPs.[188]

We propose to add the KED measure to the 2026 Star Ratings.

b. Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D)

CMS proposes to add the following measures to the 2026 Star Ratings (2024 measurement year): COB, Poly-ACH, and Poly-CNS. Additionally, the measures will include a non-substantive update: to align with the PQA measure specifications by using continuous enrollment (CE) and no longer adjusting for member-years (MYs). CMS has reported the following three Pharmacy Quality Alliance (PQA) measures for the Part D program on the 2021 display page (using 2019 data) and 2022 display page (using 2020 data) on *www.cms.gov* as announced in the Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. These measures reflect the following performance:

- Concurrent Use of Opioids and Benzodiazepines (COB) (Part D)—analyzes the percentage of Medicare Part D beneficiaries 18 years and older with concurrent use of prescription opioids and benzodiazepines.
- Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH) (Part D)—analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of two or more unique ACH medications during the measurement period.
- Polypharmacy Use of Multiple Central Nervous System-Active Medications in Older Adults (Poly-CNS) (Part D)—analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of three or more unique CNS-active medications during the measurement period.

These are important areas of focus for the Medicare Part D population. Concurrent use of opioids and benzodiazepines can increase the risk of respiratory depression and fatal overdoses.[189] [190] In addition, concurrent use of two or more unique anticholinergic medications in older adults was associated with an increased risk of cognitive decline, and the concurrent use of three or more unique CNS active medications in older adults was associated with increased risk of falls and fractures.[191] Therefore, we initially monitored these measures starting with the 2021 display page (2019 measurement year) and now propose to transition them to the Star Ratings. We anticipate that the COB, Poly-ACH, and Poly-CNS measures will continue to help plans identify enrollees who are at risk of respiratory depression or fatal overdoses, cognitive decline, or falls and fractures, respectively, and facilitate plans to encourage appropriate prescribing when clinically necessary.

We observed that the overall rates for the COB measure have slightly improved from 2021 to 2022 display page for both MA–PD and PDP contracts from 17 percent to 16 percent. For the Poly-CNS measure, MA–PD and PDP contract rates remained the same at 6 percent. Lastly in the Poly-ACH measure, we found that the MA–PD and PDP contract rates slightly increased from 8 percent to 9 percent. There is room for further improvement for all three measures. Per §§ 423.184(c)(3) and (4), new Part D measures added to the Star Ratings program must be on the display page for a minimum of 2 years prior to becoming a Star Ratings measure. In addition, the measures, as previously discussed, were submitted through the 2021 Measures Under Consideration (MUC) process, a pre-rulemaking process for the selection of quality and efficiency measures under section 1890A of the Act. These measures were reviewed by the Measure Applications Partnership (MAP) for input and recommendations to HHS on measure selection for CMS programs. All three measures received conditional approval.

We propose to add the COB, Poly-ACH, and Poly-CNS measures for the 2026 Star Ratings (based on 2024 measurement year). We will also align these three measures with the PQA measure specifications to use continuous enrollment (CE) and no longer adjust for member-years (MYs) to account for beneficiaries who are enrolled for only part of the contract year. On the display page, these three measures currently use the MY methodology; however, when the measures are transitioned to Star Ratings, the measures will not be calculated based on MY adjustment but will be calculated based on CE measure specifications defined by PQA. Based on the 2022 PQA Measure Manual, the beneficiary's index prescription start date (IPSD) begins on the earliest date of service for an opioid, ACH, or CNS-active medication, respectively, during the measurement year. Beneficiaries are continuously enrolled during the measurement year with one allowable gap of up to 31 days in enrollment during the measurement year. The change to use CE for these measures, compared to the measures as they have been used for the display page since 2021 with the MY adjustment, would be a non-substantive update under § 423.184(d)(1) because the updates do not modify the intent of the measure or the target population but may narrow the denominator population. We described these non-substantive updates here to provide complete information on the measures we propose to add to the Star Ratings and will describe the non-substantive updates in the Announcement of Calendar Year (CY)

[187] NCQA added the new Logical Observation Identifiers Names and Codes (LOINC) for the new race-free eGFR equations to the KED value sets.

[188] *https://www.cms.gov/files/document/final-2022-call-letter-qrs-qhp-enrollee-survey.pdf.*

[189] US Food and Drug Administration. FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning [internet]. 2016 [2016 Nov 9]. Available at *http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm.*

[190] Centers for Disease Control and Prevention. Drug Overdose Deaths. N.d. Available at *https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html.*

[191] American Geriatrics Society 2019 Beers Criteria Update Expert Panel. Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019 Apr;67(4):674–694. PMID: 30693946.

2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies as required by § 423.184(d)(1).

We solicit comments on adding the three Part D measures to the Star Ratings.

Table 4 summarizes the additional and updated measures addressed in this proposed rule for the 2026 Star Ratings, unless otherwise noted. The measure descriptions listed in this table are high-level descriptions. The annual 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, Stars Ratings for the year 2026 are produced in the fall of 2025. If a measurement period is listed as ''the calendar year 2 years prior to the Star Ratings year'' and the Star Ratings year is 2026, the measurement period is referencing the January 1, 2024 to December 31, 2024 period.

Table 4. Summary of Proposed New and Revised Individual Star Rating Measures for Performance Periods Beginning on or after January 1, 2024

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part C Measures								
Colorectal Cancer Screening (COL)*	Percent of plan members aged 45 to 75 who had appropriate screenings for colorectal cancer.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	#0034	Clustering	MA-PD and MA-only
Kidney Health Evaluation for Patients with Diabetes (KED)	Percent of plan members ages 18-85 with diabetes (type 1 and type 2) who received a kidney health evaluation during the measurement year.	Managing Chronic (long term) conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only
Care for Older Adults (COA) – Functional Status Assessment*	Percent of Special Needs Plan enrollees 66 years and older who received a functional status assessment	Managing Chronic (long term) conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	Special Needs Plans
Part D Measures								
Medication Adherence for Diabetes Medication*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for diabetes medications during the measurement year.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
Medication Adherence for Hypertension (RAS Antagonists)*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC) threshold of 80% for RAS antagonists during the measurement year.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
Medication Adherence for Cholesterol (Statins)*++	The percentage of individuals > 18 years of age who met the Proportion of Days Covered (PDC)	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
	threshold of 80% for statins during the measurement year.							
Concurrent Use of Opioids and Benzodiazepines (COB)	The percentage of individuals ≥18 years of age with concurrent use of prescription opioids and benzodiazepines.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	#3389	Clustering	MA-PD and PDP
Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)	The percentage of individuals ≥65 years of age with concurrent use of ≥2 unique anticholinergic medications.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Polypharmacy Use of Multiple Central Nervous System-Active Medications in Older Adults (Poly-CNS)	The percentage of individuals ≥65 years of age with concurrent use of ≥3 unique central-nervous system (CNS)-active medications.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP

*Revised Measures

++Updates for 2028 Star Ratings (2026 Measurement Year)

We welcome comments on the measure updates and additions.

4. Revising the Rule for Non-Substantive Measure Updates (§§ 422.164(d) and 423.184(d))

We are proposing to add collection of survey data through another mode of survey administration to the non-exhaustive list of non-substantive measure updates that can be made without rulemaking. The rules CMS adopted to address measure updates based on whether an update is substantive or non-substantive are specified at §§ 422.164(d) and 423.184(d). As described at 83 FR 16534, we incorporate updates without rulemaking for measure specification changes that do not substantively change the nature of the measure. In paragraphs (d)(1)(i)–(v) of §§ 422.164 and 423.184, we provided a non-exhaustive list of circumstances that would constitute a non-substantive update. Currently, paragraph (d)(1)(v) of each regulation identifies the addition of an alternative data source as a non-substantive update; the proposed additional example is the collection of alternative data sources or expansion of modes of data collection. These two examples are similar but not exactly the same, so we are proposing to clarify in the regulation that an expansion in the data sources used, whether by adding an alternative source of data or adding an alternative way to collect the data, is a non-substantive change in measure specifications. The expansion of how data are collected is non-substantive because there would be no change to the information that is being collected; the only change would be the way in which it is collected. For example, if a web mode of survey administration is added to the current mail with telephone follow-up of non-respondents survey administration that is currently used for CAHPS and HOS, this would be considered a non-substantive change that could be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act since this does not change what is being measured, but just expands the way the data can be collected.

We propose to revise the regulation text at §§ 422.164(d)(1)(v) and 423.184(d)(1)(v) by adding that another example of a non-substantive change would include a new mode of data collection.

We welcome comments on this proposal.

5. Measure Removal (§§ 422.164(e)(1) and 423.184(e)(1))

CMS proposes adding a new rule for measure removal. We propose that CMS will have the authority to remove a measure from calculations of Star Ratings when a measure steward other than CMS retires the measure. CMS continually reviews measures that are used in calculations of Star Ratings. As codified at §§ 422.164(e)(1) and 423.184(e)(1), CMS may remove a measure (1) when the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes, or (2) when a measure shows low statistical reliability. See also 83 FR 16533–16537. In both of these circumstances, as codified at §§ 422.164(e)(2) and 423.184(e)(2), CMS will announce the removal of any measure in advance of the measurement period through the process described for changes in and adoption of payment

and risk adjustment policies in section 1853(b) of the Act.

We propose adding a rule at §§ 422.164(e)(1)(iii) and 423.184(e)(1)(iii) to allow removing a Star Ratings measure for another reason. We propose that when a measure steward other than CMS (for example, NCQA or PQA) retires a measure, CMS will have the authority to remove the measure from calculations of Star Ratings through the process described at §§ 422.164(e)(2) and 423.184(e)(2). When a measure steward such as NCQA retires a measure, they go through a process that includes extensive review by their various measurement panels and they solicit public comment regarding proposed measure retirements so health plans, purchasers, consumers and other stakeholders have an opportunity to weigh in on the relevance and scientific soundness of any changes to the HEDIS measurement set. This proposal will allow CMS to respond more quickly to measure removals by external measure stewards to ensure that measures included in Star Ratings are clinically meaningful, reliable, and up-to-date. We solicit comment on this proposal.

E. Measure Weights (§§ 422.166(e) and 423.186(e))

1. Patient Experience/Complaints and Access Measures (§§ 422.166(e)(1)(iii) and (iv), 423.186(e)(1)(iii) and (iv))

CMS is proposing to lower the weight of patient experience/complaints and access measures to 2 beginning with the 2026 Star Ratings covering the 2024 measurement period. The weight for the patient experience/complaints and access measures is codified at §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv). Process measures receive a weight of 1, outcome measures receive a weight of 3, and the Part C and D Improvement measures receive a weight of 5. In the April 2018 final rule, we finalized an increase in the weight of patient experience/complaints and access measures from 1.5 to 2, starting with the 2021 Star Ratings. (83 FR 16575–77). These 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. We also 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 intended to further increase the weight of patient experience/complaints and access measures in the future. In the June 2020 final rule, CMS finalized an additional increase in the weight of patient experience/complaints and access measures from 2 to 4 for the 2023 Star Ratings. At that time, we said we were putting more weight on this category of measures that primarily reflect patient experience of care measures to put patients first and to emphasize CMS's goal of listening to the voice of the patient to identify opportunities to improve care delivery. (85 FR 33837) We still believe these measures focus on critical aspects of care such as care coordination and access to care from the perspective of enrollees, but taking into consideration additional stakeholder feedback we have received and the effect of the policy on the 2023 Star Ratings, we have reconsidered our position from the June 2020 final rule and now believe these measures currently receive an undue weight in the Star Ratings program.

One of the guiding principles of the Part C and Part D Star Ratings program is to align with the CMS Quality Strategy (83 FR 16521). As part of the current CMS Quality Strategy, CMS is trying to create a resilient, high-value health care system that promotes quality outcomes, safety, equity, and accessibility for all individuals, as described at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.* One of the goals of the CMS Quality Strategy is to increase alignment across the CMS quality programs to improve value. Currently, the measure weight of 4 for the patient experience/complaints and access measures is not consistent with the contribution of these types of measures in the overall performance scores for other CMS quality measurement programs. For example, in the hospital value-based purchasing program, person and community engagement measures which are measures collected through the Hospital CAHPS Survey account for 25 percent of the total performance score for hospitals (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospital-value-based-purchasing-*). As another example, one-sixth of the global score for the Quality Rating System for QHPs is based on enrollee experience (*https://www.cms.gov/files/document/2022-qrs-and-qhp-enrollee-survey-technical-guidance.pdf*). In contrast, for the 2023 Star Ratings, with a weight of 4, the patient experience/complaints and access measures account for approximately 58 percent of the overall rating for MA–PDs. For the Part C and Part D Star Ratings, we include a broader set of measures related to person and community engagement relative to other CMS quality programs. For example, we include appeals measures given the importance of access to care and services for Part C plan enrollees. However, if the patient experience/complaints and access measures had a weight of 2, these measures would account for 41 percent of the overall rating. Reducing the weighting to 2 for this category of measures would align the patient experience/complaints and access measures more closely with other programs, without exactly matching the lower influence measures of this type have on the overall (that is, total performance or global) score in these other programs. We are not proposing to reduce the weight further than 2 given the important link between patient experience, adherence, and health outcomes. Reducing the weight for these measures from 4 to 2 is a significant change and a more extensive change may be too much to adopt at this time. Prior to the April 2018 final rule, the weight of 1.5 given to the patient experience/complaints and access measures in the Part C and Part D Stars Ratings had been in place since the 2012 Star Ratings, so we have extensive experience with how using a weight lower than 2 for these categories of measures influence plan behavior. We continue to believe that a weight higher than 1.5 is appropriate.

The weighting of measures within the Star Ratings program is important as not all measures contribute equally to the goals of the program. Patient experience, complaints, and access to care have been linked to improved clinical outcomes and are important aspects of health care. For example, patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital patient safety culture, better clinical outcomes, reduced unnecessary health care use, and fewer inpatient complications (Anhang Price et al., 2014; Anhang Price et al., 2015; Quigley et al., 2021).[192] We also

[192] Anhang Price, R., Elliott, M.N., Zaslavsky, A.M., Hays, R.D., Lehrman, W.G., Rybowski, L., Edgman-Levitan, S., & Cleary, P.D. (2014). Examining the role of patient experience surveys in measuring health care quality. Medical Care Research and Review, 71(5), 522–554.

Anhang Price, R., Elliott, M.N., Cleary, P.D., Zaslavsky, A.M., & Hays, R.D. (2015). Should health care providers be accountable for patients' care experiences? Journal of General Internal Medicine, 30(2), 253–256.

Quigley D.D., Reynolds K., Dellva S., & Anhang Price, R. (2021). Examining the business case for

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recognize that whether clinicians acknowledge patient preferences [193] may be another factor that is important to measure and include in the Star Ratings program; consequently, we are currently testing a question for the CAHPS survey related to whether an enrollee's personal doctor dismisses symptoms that are important to them for potential incorporation in the survey and Star Ratings in the future. CMS continues to believe, as we stated in the April 2018 final rule at 83 FR 16576, that we must listen to the perceptions of care from people with Medicare, as well as ensure they have access to needed care. While focusing on patient experiences of care and ensuring that care is person-centric are critical, health and drug plans also have a responsibility to consider and work toward improving clinical outcomes. Improving clinical outcomes is an important goal for the Part C and Part D programs to meet the CMS Quality Strategy goal of promoting the highest quality outcomes and safest care for all individuals. High-value care does not always align with patient experiences of care, and we must take this into consideration as we consider how to weight the different Star Ratings measures. Clinical quality measures, for example, are also important in that they measure health outcomes, clinical processes and adherence to clinical guidelines. They measure whether plans are following the best practices for healthcare delivery, including providing preventive care such as immunizations and cancer screenings and caring for enrollees with ongoing health problems such as diabetic enrollees who need blood sugar tests, eye exams and blood pressure monitoring. It is also important to create incentives for health and drug plans to continuously focus on quality improvement by giving sufficient weight to the Health Plan Quality Improvement and Drug Plan Quality Improvement measures relative to the patient experience/access and complaints measures. We believe the weight given to measures in the Part C and Part D Star Ratings program should be in line with the how the measures are linked to health care and the value they have in improving health care.

Subsequent to finalizing the weight of 4 for patient experience/complaints and access measures in the June 2020 final rule, we have received significant stakeholder feedback on this issue through the Part C and D Advance Notices, the 2023 Part C and D proposed rule (CMS–4192–P), the COVID–19 interim final rules (CMS–1744–IFC and CMS 3401–IFC), letters sent to CMS and meetings with plans. A number of concerns have been raised by stakeholders related to a weight of 4, including devaluing measures of health outcomes, encouraging plans to abandon efforts to drive clinically appropriate care, sending the message that preventive care such as cancer screenings are not important, and not balancing appropriately clinical excellence and patient experience. Stakeholders have also raised concerns around disproportionately overweighting patient experience measures which in turn diminishes the importance of other measures. MedPAC noted in their response to the CY 2021 and 2022 proposed rule (CMS–4190–P) that the increased weight would give disproportionate weight to patient experience measures relative to outcome measures and create an imbalance between the two most important measure groupings—outcome and patient experience measures. Stakeholders have continued to raise concerns about the disproportionate weight given to patient experience/complaints and access measures. Stakeholders have continued to suggest that clinical outcomes should count more than patient experience of care measures. Additionally, we have received feedback that cancer screenings, medication reconciliation, and other Star Ratings measures are critical areas of focus in particular in underserved communities but have a diminished role in the Star Ratings program due to the high weight of patient experience/complaints and access measures.

Given these concerns, as well as the impact of the weighting policy on the 2023 Star Ratings, CMS is re-evaluating its decision to weight these measures higher than outcome measures. We are concerned that the higher weight of 4 may create incentives for plans to not focus as much on patient outcomes, screenings, and preventive care. This could lead to ineffective or inappropriate care and increased costs if providers primarily focus on patient experiences. Although patient experience/complaints and access to care measures have been linked to improved clinical outcomes and are important aspects of health care, we are proposing to move back to a weight of 2 to more appropriately balance the value these measures contribute to achieving high quality care without weighting them higher than clinical outcome measures and to better align the total contribution of patient experience and outcome measures with other CMS quality reporting programs.

To better align the Part C and Part D Star Ratings with the current CMS Quality Strategy and other CMS quality programs and to better balance the contribution of the different types of measures in the Star Ratings program, we propose to modify § 422.166 at paragraphs (e)(1)(iii) and (iv) and § 423.186 at paragraphs (e)(1)(iii) and (iv) to decrease the weight of patient experience, complaints, and access measures from 4 to 2 beginning with the 2026 Star Ratings. At a weight of 2, the patient experience, complaints, and access measures would be weighted higher than process measures but not as high as outcome measures. This is in line with the value these measures add to achieving high quality care without weighting them higher than clinical outcome measures. In addition, this would align more closely with the weight these types of measures are given in other CMS quality programs.

We welcome feedback on this change.

2. Weight of Measures With Substantive Updates (§§ 422.166(e)(2) and 423.184(e)(2))

We are proposing to adopt regulation text clarifying how we treat measures with substantive updates when they return to the Star Ratings program. The general rules that govern updating measures are specified at §§ 422.164(d) and 423.184(d), including rules for non-substantive and substantive measure updates. As described at 83 FR 16534, the process for adopting substantive measure specification updates is similar to the process for adopting new measures. Historically, we have treated measures with substantive updates as new measures when they are added back to the Star Ratings following two or more years on the display page and adoption through rulemaking.

Currently, new measures receive a weight of 1 for their first year in the Star Ratings program as specified at §§ 422.166(e)(2) and 423.186(e)(2). We propose to add language to §§ 422.166(e)(2) and 423.186(e)(2) to clarify that when a measure with a substantive update moves back to Star Ratings from the display page following rulemaking, it is treated as a new measure for weighting purposes and therefore would receive a weight of 1 for its first year back in the Star Ratings program. This is consistent with our current and prior practice and with the explanation provided in the January 2021 final rule about the weight

patient experience: a systematic review. Journal of Healthcare Management, 66(3), 200–224.

[193] Cohen, Marc A., Hwang, Ann and Hawes, Frances M. (July 13, 2022). Could Person-Centered Care Be The Secret To Achieving the Triple Aim? Health Affairs Forefront.

provided to substantively updated measures for the first year they are returned to the Star Ratings (86 FR 5919). In subsequent years, the measure (both new measures and substantively updated measures) would be assigned the weight associated with its category, which is what happens with new measures as well. In addition, we are proposing to revise the heading for paragraph (e)(2) to reflect how the provision addresses the weight of both new and substantively updated measures.

We welcome comments on this proposal.

F. Guardrails (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by adding guardrails, which are measure-specific caps to Star Ratings cut points in both directions so that the measure-threshold-specific cut points do not increase or decrease more than the value of the cap from one year to the next. The intent of this change in methodology was to increase the predictability and stability of cut points. As described in the April 2019 final rule at 84 FR 15754, a trade-off of increasing the predictability of cut points is the inability to keep pace with any unanticipated changes in industry performance. Based on recent experience with calculating Star Ratings during the COVID–19 PHE and analyses of the data for the 2022 Star Ratings, we are proposing to modify the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by eliminating the guardrails that restrict the maximum allowable movement of non-CAHPS measure cut points.

When we initially proposed guardrails so that the cut points for non-CAHPS measures do not increase or decrease more than the cap from one year to the next, we recognized that with guardrails there may be an inability for thresholds to fully keep pace with changes in performance across the industry. A cap on upward movement can inflate the measure-level Star Ratings if true improvements in performance cannot be fully incorporated in the current year's ratings. If overall industry performance shifts upward on a measure, the Star Ratings cut points affected by a cap for that measure may not fully take into account this upward shift in industry performance. While we recognized the possibility at the time we finalized the guardrails policy, we now have evidence from the 2022 and 2023 Star Ratings that shows that unintended consequence of the policy. For example, for the 2023 Star Ratings for Part C Osteoporosis Management in Women who had a Fracture, the four star threshold without the cap was greater than or equal to 60 percent, but this threshold was reduced to greater than or equal to 55 percent when guardrails were applied. In effect, the cap makes it easier for contracts to receive four stars than it would have been if there was no cap. In this example, because of the cap, a contract with performance of 57 percent would receive a four star rating when, without the cap, the contract would receive a three star rating. This is diluting the value of receiving four stars for contracts that would have received four stars without the cap since some contracts received four stars for performance that ordinarily would not qualify for four stars. Conversely, a cap on downward movement can decrease the measure-level Star Ratings when industry performance overall shifts downward, since the ratings cannot be adjusted fully for downward shifts in performance. For example, for the 2023 Star Ratings for Colorectal Cancer Screening, the one star cut point was higher (43 percent) than it would have been without a cap (38 percent), and therefore more contracts received a one star rating on that measure than they would have if there were no cap. During the COVID–19 PHE, we saw that industry performance declined on some measures included in the 2022 Star Ratings and for other measures industry performance increased. In order to allow non-CAHPS cut points to move with these changes in industry performance, we adopted a delay in the implementation of guardrails in the interim final rule titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' which appeared in the **Federal Register** on April 6, 2020 with a March 31, 2020 effective date [194] at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i).

The intent of guardrails was to improve predictability and stability of cut points from one year to the next. At the time the addition of guardrails to the Star Ratings methodology was finalized, we also finalized the addition of mean resampling to the hierarchical clustering methodology to reduce the sensitivity of the clustering algorithm to outliers and reduce the random variation that contributes to fluctuations in cut points. Mean resampling was implemented beginning with the 2022 Star Ratings. Since the addition of guardrails was finalized, we also finalized in the June 2020 final rule at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) adding Tukey outlier deletion to the hierarchical clustering methodology to improve the predictability and stability of cut points. (85 FR 33833–36). Tukey outlier deletion will be implemented beginning with the 2024 Star Ratings and will remove extreme outliers before the clustering algorithm is applied; this will improve the predictability and stability of cut points, which in turn minimizes the need for the guardrails to achieve such goals and weakens the rationale of the guardrails policy at the time the policy was finalized.

After the April 2019 final rule was published, we have learned during the COVID–19 pandemic that it is important for cut points to adjust for unforeseen circumstances that may cause overall industry performance to either increase or decrease. During the 2020 measurement year, we saw both significant increases and significant decreases in scores across some of the Star Ratings measures.[195] As an example, there was a significant shift downward in performance for the Breast Cancer Screening measure during the 2020 measurement year. For Breast Cancer Screening, the 5-star cut point for the 2021 Star Ratings was greater or equal to 83 percent, while for the 2022 Star Ratings it was greater or equal to 76 percent. This drop in the 5-star cut point reflects the change in industry performance. If bi-directional guardrails had been applied for the 2022 Star Ratings, this cut point would have been 78 percent rather than 76 percent, resulting in more contracts earning 4 stars rather than the 5 stars that they would have earned when compared to the performance of their peers in the absence of guardrails. Similarly, there was a significant shift downward in performance for the Diabetes Care—Eye Exam measure during the 2020 measurement year. For Diabetes Care—Eye Exam the 1-star cut point for the 2021 Star Ratings was less than 63 percent, while for the 2022 Star Ratings it was less than 52 percent. This significant drop in the 1-star cut point reflects the downward shift in industry performance. If bi-directional guardrails had been applied for the 2022 Star Ratings, this cut point would have been 58 percent, resulting in some contracts earning 1 star for this measure rather

[194] *www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public.*

[195] 2022 Star Ratings Fact Sheet. *https://www.cms.gov/files/document/2022-star-ratings-fact-sheet1082021.pdf.*

than 2 stars when compared to the performance of their peers in the absence of guardrails. There was also a significant shift upward in performance for the MTM Program Completion Rate for CMR for PDPs during the 2020 measurement year. The MTM 5-star cut point for the 2021 Star Ratings was greater than or equal to 61 percent, while for the 2022 Star Ratings it was greater than or equal to 74 percent. This increase in the 5-star cut point reflects the change in industry performance. If bi-directional cut points had been applied for the 2022 Star Ratings, this cut point would have been 66 percent rather than 74 percent resulting in more contracts receiving 5 stars. These examples from the 2020 measurement year have led us to believe that bi-directional guardrails can inappropriately limit the ability of cut points to shift when there are unanticipated shifts in industry performance, causing misclassification in the measure-level Star Ratings assignments.

In addition, the combination of mean resampling and Tukey outlier deletion, with Tukey outlier deletion being finalized after the bi-directional guardrails policy, will provide sufficient predictability and stability of cut points from one year to the next when there are not significant changes in overall industry performance, but at the same time allow cut points to adjust when there are significant changes in performance as there was during the COVID–19 pandemic. We believe it is important for cut points to be allowed to shift by more than 5 percentage points when there are unanticipated, large changes in industry performance in the future. We are proposing at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to modify the language so that guardrails for non-CAHPS measures will only be effective through the 2025 Star Ratings released in October 2024, and not apply for the 2026 Star Ratings or beyond.

We welcome feedback on these changes.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

As discussed in section III.A of this proposed rule, advancing health equity is the first pillar of the 2022 CMS Strategic Plan and a goal of the CMS national quality strategy. In reports on accounting for Social Risk Factors (SRFs) in value-based purchasing programs, the National Academies of Sciences, Engineering, and Medicine (NASEM) define Social Risk Factors (SRFs) as factors related to health outcomes that are evident before care is provided, are not consequences of the quality of care, and are not easily modified by healthcare providers.[196] CMS agrees with the NASEM definition of SRFs because it captures the elements we consider important in defining SRFs. There are often disparities in health care and outcomes between groups with and without social risk factors (SRFs). For example, the within-contract LIS/DE and non-LIS/DE differences in performance for Part C and D Star Ratings measures can be found at: *2022 Categorical Adjustment Index Measure Supplement Dec 10 2020 (cms.gov).*

The current approach to addressing SRFs in the Part C and Part D Star Ratings program has focused on adjusting for the average within-contract disparities in performance through the Categorical Adjustment Index (CAI), as described at §§ 422.166(f)(2) and 423.186(f)(2), in order to not inappropriately penalize or reward health and drug plans for factors that are difficult for plans to control. For certain current Star Ratings measures, it may be more difficult for most plans to achieve the same level of care for groups that are socioeconomically disadvantaged, disabled, or more complex due to a variety of issues, including transportation issues, lower health literacy, communication challenges, and residential instability. The CAI is a factor that can be positive or negative and is added to a contract's overall and summary Star Ratings that adjusts for the average within-contract performance disparity based on a contract's composition of Low Income Subsidy/Dual Eligible (LIS/DE) and disability status enrollees.

The CAI was implemented in the Part C and Part D Star Ratings program to address SRFs while measure stewards evaluated adjustment on a measure-specific basis. The CAI is a data-driven approach to account for within-contract disparities in performance associated with SRFs in Star Ratings measures that are not already adjusted according to the measure specifications developed by measure stewards. The CAI does not incentivize contracts to focus on reducing disparities. Although all contracts have incentives in the Star Ratings program to improve performance, there are currently no methodological adjustments that specifically create incentives to address disparities of care among a contract's enrollees.

In addition to adjusting for within-contract disparities through the CAI, we also want to encourage MA organizations, cost plans, and Part D plan sponsors to better identify and then address disparities in care provided to enrollees with a particular SRF, with the ultimate goal of reaching equity by eliminating health disparities or differences in contract performance by SRFs, consistent with CMS efforts to advance health equity.

CMS has developed a health equity index (HEI) that we are proposing for use in the Part C and Part D Star Ratings that would reward contracts for obtaining high measure-level scores for the subset of enrollees with specified SRFs. Our intent in implementing an HEI is to improve health equity by incentivizing MA, cost plan, and PDP contracts to perform well among enrollees with specified SRFs. The CAI is designed to improve the accuracy of performance measurement, while not masking true differences in performance between contracts; in contrast, our proposed HEI reward is specifically designed to create an incentive to reduce disparities in care. The HEI, therefore, does not replace the CAI but rather assists plan sponsors in better identifying and then addressing disparities in care provided to members with a particular SRF, with the ultimate goal of reaching equity in the level and quality of care provided to enrollees with SRFs. There would be no changes to the current CAI with the implementation of the proposed HEI reward.

We are proposing to replace the current reward factor described at §§ 422.166(f)(1) and 423.186(f)(1) with the new HEI reward at proposed §§ 422.166(f)(3) and 423.186(f)(3) starting with the 2027 Star Ratings; the HEI for the 2027 Star Ratings would be calculated using data collected or used for the 2026 and 2027 Star Ratings. The current reward factor was included in the Part C and Part D Star Ratings program beginning with the 2009 Star Ratings with the purpose of creating additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures (that is, a mix of low performance and high performance across measures). At the beginning of the Star Ratings program, the distribution of ratings across contracts looked very different, with overall performance much lower than it is today. Over time, we have established additional methodological enhancements to incentivize performance improvement across

[196] Social Risk Factors: Definitions and Data √ Accounting for Social Risk Factors in Medicare Payment √The National Academies Press | *https://nap.nationalacademies.org/read/23635/chapter/4.*

measures, such as the addition of the Health Plan Quality Improvement and the Drug Plan Quality Improvement measures as described at §§ 422.164(f) and 423.184(f). MA organizations have also responded to the incentive to perform well across measures as a result of the link between Star Ratings and Quality Bonus Payment ratings for MA contracts. CMS believes if we finalize the removal of the current reward factor from the Star Ratings methodology, contracts would still have incentives to perform well and improve because high performance on individual Star Ratings measures, including the Health Plan Quality Improvement and the Drug Plan Quality Improvement measures, translates into better overall and summary ratings. The removal of the current reward factor is contingent on finalizing the addition of the proposed HEI reward.

CMS is proposing to add the HEI reward as a methodological enhancement to the Part C and Part D Star Ratings program starting with the 2027 Star Ratings because, similar to the current reward factor, it provides a summary of how performance varies across existing Star Ratings measures. The proposal to add the HEI reward is a methodological enhancement using data from existing Star Ratings measures; it is not a proposal to add a new measure with additional burden for contracts. In the case of our proposed HEI, however, this summary of performance would be based on performance related to a subset of enrollees with specified SRFs. Adding the HEI as a reward also allows for the methodology to include a performance threshold below which contracts will not be eligible for the HEI reward, which will incentivize improved performance by contracts for their enrollees with the specified SRFs and help reduce disparities. CMS could also potentially increase this performance threshold over time to incentivize continued efforts to reduce disparities in care.

In developing the proposed HEI reward, we considered a number of goals to ensure the incentives of the HEI and the associated reward were in line with our intent. We aim to improve health equity by incentivizing MA plans, cost plans, and Part D plan sponsors to perform well among enrollees with certain SRFs. These goals include:

- Avoiding rewarding large contracts over small contracts that may be providing high quality care for enrollees with the SRFs included in the HEI but lack the number of enrollees needed to reliably calculate the HEI.
- Avoiding rewarding contracts that may do well among enrollees with the SRFs included in the HEI but serve very few enrollees with those SRFs, making it easier to do well.
- Only rewarding contracts that have high relative performance among enrollees with the SRFs included in the HEI compared to other contracts to incentivize high performance for enrollees with the SRFs included in the HEI.
- Ease of use and understanding for contracts and other stakeholders.
- Minimizing the number of years of data needed to calculate the HEI and HEI reward such that the data used are as current as possible.
- Allowing for updates to the measure set included in the HEI and updates to accommodate the addition of other SRFs to the HEI over time.
- Promoting improvement in performance and enrollment of individuals with certain SRFs in MA plans, cost plans, and Part D plans.
- Accurately reflecting true performance among contracts serving enrollees with certain SRFs and minimizing sensitivity to measurement error.

The proposed HEI would summarize contract performance in relation to enrollees with certain SRFs across multiple existing Star Ratings measures into a single score using data from the most recent two measurement years. We propose at §§ 422.166(f)(3)(i)(A) and 423.186(f)(3)(i)(A) to initially include receipt of the LIS or being dually eligible (LIS/DE) or having a disability as the group of SRFs used to calculate the HEI. Prior research has shown that dual eligibility is one of the most influential predictors of poor health outcomes, and disability is also an important risk factor linked to health outcomes.[197] The SRFs included in the HEI may be expanded over time. For purposes of the HEI, we propose to define an LIS/DE beneficiary as one who was designated as a full-benefit or partial-benefit dually eligible individual or who received a low-income subsidy (LIS) at any time during the applicable measurement period, as we do currently for the calculation of the CAI. If a person meets the criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. We intend to use the original reason for entitlement to the Medicare program to identify enrollees with a disability for purposes of the HEI as we do for the calculation of the CAI.

We are interested in feedback on potential additional ways to identify enrollees who have a disability that could be incorporated over time and whether the same process and standards should be used for the CAI adjustment as well. In particular, we are interested in how we could expand the definition to include enrollees who develop a disability after aging into the Medicare program. LIS/DE and disability are the SRFs that have been used in the CAI for many years and are included in the confidential Part C and D Stratified Reports provided to MA and Part D contracts in HPMS as of 2022. As currently proposed, enrollees with these SRFs will be identified for the HEI the same way they are identified for the CAI at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B).

We also considered including the Area Deprivation Index (ADI) in the HEI at this time. The ADI is a measure of socioeconomic neighborhood deprivation, including measures of income, employment, housing, education, social environment, and readmissions. However, consistent with literature on the ADI, and other neighborhood-based indices,[198] our analyses showed the ADI explains very little of the variation in the quality of care received beyond enrollee-level LIS/DE and disability information. We will continue to explore the feasibility of adding other SRFs to the HEI over time. The addition of other SRFs or other mechanisms to identify enrollees with one or more of the SRFs that are part of the proposed HEI would be proposed through future notice-and-comment rulemaking.

The proposed HEI would examine performance among those with certain SRFs for all Star Ratings measures unless they meet one of the specified exclusions. As provided in proposed §§ 422.166(f)(3)(ii)(A)–(D) and 423.186(f)(3)(ii)(A)–(D), measures would be excluded from the HEI if one or more of the following criteria are met:

- The focus of the measurement is not the enrollee but rather the plan or provider (for example, the appeals and call center measures focus on the plan and its operations rather than on the enrollee). Measures meeting this criterion would be excluded because enrollee-level SRF information for these

[197] *https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?_ga=2.49530854.1703779054.1662938643-470268562.1638986031.*

[198] Beckett MK, Martino SC, Agniel D, Mathews M, Hudson Scholle S, James C, Wilson-Frederick S, Orr N, Darabidian B, Elliott MN. (2021). ''Distinguishing neighborhood and individual social risk factors in health care'' *Health Services Research:* 1–14.

measures is not available for inclusion in the HEI.

- The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI. Measures meeting these criteria would be excluded because there is not enough data to calculate the HEI for these measures.
- The measure is applicable only to SNPs. Measures meeting this criterion would be excluded because these measures are not relevant for all contracts.
- At least 25 percent of contracts are unable to meet the criteria described at proposed paragraph (f)(3)(iv), which provides that a measure is only included for the HEI for a contract if the measure has a reliability of at least 0.7 for the contract when calculated for the subset of enrollees with the specified SRF(s) and the contract meets the measure denominator requirement when the measure is calculated for only the enrollees with the specified SRF(s) (that is, the SRFs included in the HEI). For Part D measures, this criterion is assessed separately for MA–PDs and cost contracts, and PDPs. We are proposing to exclude any measures from the HEI that less than 25 percent of contracts can have reliably calculated because scores would be missing for most contracts.

As proposed at §§ 422.166(f)(3)(iii) and 423.186(f)(3)(iii), the measures being evaluated for inclusion in the HEI would be announced annually in the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. These announcements (of the measures being evaluated for inclusion in the HEI) will not include the final list of measures used in the HEI for the upcoming Star Ratings because the data to determine that final set would not yet be available. In general, measures from HEDIS, HOS, and CAHPS would be included unless they meet one of the exclusion criteria, as previously described. Additionally, medication adherence, MTM Program Completion for CMR, and Statin Use in Persons with Diabetes measures would be included as long as they meet the requirements for inclusion for more than 25 percent of contracts.

In this section of this rule, we propose each of the five steps that CMS would take to analyze the measure-level scores for each contract and to roll up to the HEI scores in order to assess when an adjustment is available for a contract's ratings.

Step 1: For each measure included in the HEI, measure-level scores calculated for each contract among enrollees with the included SRFs (that is, all enrollees who are DE, LIS, or disabled combined into one group) would be combined over the two most recent measurement years. CMS carefully considered the number of years of data needed for the proposed HEI. We believe that using 2 years of data allows for a balance between increasing measure-level reliability so that smaller contracts may still have enough data to have the HEI calculated and minimizing the number of years of data used. As outlined in our goals in designing the HEI, it is important to minimize the number of years of data used to avoid carrying forward very old data in the Star Ratings and to allow new measures and newer contracts to more quickly be included in the HEI.

As proposed at §§ 422.166(f)(3)(i)(B) and 423.186(f)(3)(i)(B), the scores for the subset of enrollees with SRFs of interest included in the HEI would be calculated using a modeling approach that includes year (that is, an indicator for whether the data are from year 1 or year 2) as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Scores are adjusted for year to account for situations where mean scores were, for the average contract, different in the 2 years (for example, higher in year 2 than year 1, or vice versa) and for contracts that have measure sample sizes that differ across years. Data will be used for contracts that have data for only the most recent year of the 2 years, but data will not be used for contracts that have data for only the first of the 2 years in order to ensure use of the most current data possible.

Step 2: Measures that are case-mix adjusted in the Star Ratings would be adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest. The CAHPS measures included in the Star Ratings are currently adjusted for DE and LIS. For the proposed HEI, for the subset of enrollees who are DE, LIS, or disabled in Step 1, we would not include the case-mix adjustment for DE and LIS when calculating the scores over the 2-year period for the CAHPS measures. If the proposal to implement risk adjustment for the three Star Ratings medication adherence measures based on the PQA specifications in section V.D.2.c. of this proposed rule is finalized, then we would not include risk adjustment for DE, LIS, and disabled enrollees when calculating the scores over the 2-year period as described in Step 1.

Step 3: For a measure to be included in the HEI for a specific contract, both of the following inclusion criteria in proposed §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv) would need to be met: (1) reliability of at least 0.7 when the measure is calculated for the combined subset of enrollees with the specified SRFs across 2 years of data, and (2) measure-specific denominator criterion (for example, HEDIS measures require a minimum denominator of at least 30) is met when the measure is calculated for the combined subset of enrollees with the specified SRFs across 2 years of data. We are proposing at paragraph (f)(3)(vi) that contracts would also need to have at least 500 total enrollees at the contract level in the most recent measurement year used in the HEI. We are proposing a minimum in order to have reliable measure-level scores. For many of the Star Ratings measures (for example, HEDIS and HOS measures) at least 500 enrollees are needed to have a sufficient number of enrollees to reliably measure the performance of the contract.

Step 4: As we propose in §§ 422.166(f)(3)(v) and 423.186(f)(3)(v), to calculate the HEI score assigned to a contract, the distribution of contract performance on each eligible measure among enrollees with the specified SRFs (that is, all enrollees who are DE, LIS, or disabled combined into one group) would be calculated and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving –1 point for each measure. For example, for the Breast Cancer Screening measure, we would calculate performance for all contracts for the enrollees with one or more of the specified SRFs (that is, for the enrollees who are DE, qualify for LIS, and/or are disabled) using the two most recent measurement years. We would then look at the distribution of scores for this measure for all contracts that have at least 0.7 reliability and meet the minimum denominator size for the measure. Contracts that score in the top third of all contracts would receive 1 point for this measure, the middle third of contracts would receive 0 points for this measure, and the bottom third of contracts would receive 1 negative point for this measure. The same analysis would be repeated for each measure included in the HEI.

Step 5: For each contract, the HEI would then be calculated as the weighted average of these points using the Star Ratings measure weights and

including only measures for which the contract met all of the inclusion criteria specified at §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv). The weighted average would be the weighted sum of points across all included measures divided by the weighted sum of the number of included measures. We propose to use the weight for the measure in the current Star Ratings year. For example, if the HEI were being calculated using data from the 2026 and 2027 Star Ratings year, the measure weight used would be the weight for the 2027 Star Ratings. To ensure that the HEI is not driven by a very small number of measures for some contracts, we are proposing at §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi) that a contract must meet the reliability and denominator criteria for at least half of the measures included in the HEI in order to have the HEI calculated for the contract. Contract performance on the HEI would vary from −1.0 (performance was in the bottom third for each included measure) to 1.0 (performance was in the top third for each included measure).

Table 5 is a high-level summary of the steps CMS is proposing to take to calculate the HEI.

TABLE 5: STEPS TO CALCULATE THE HEI

Steps	High-Level Description of Steps to Calculate the HEI
Step 1	Measure-level scores for each measure included in the HEI are calculated for each contract using data from the two most recent measurement years based on enrollees with the specified SRFs using a modeling approach that accounts for year.
Step 2	Measures that are case-mix adjusted in the Star Ratings would employ all standard case-mix adjustors except for adjusters that are the same as the SRFs included in the HEI, are strongly correlated with the included SRFs, or are conceptually similar to the included SRFs.
Step 3	A contract would need to meet the reliability and minimum denominator criteria for at least half of the measures included in the HEI based on data from the two most recent measurement years and have at least 500 enrollees at the contract level in the most recent measurement year to have the HEI calculated.
Step 4	For each measure using all contract-level scores calculated in Step 1/Step 2 that have at least 0.7 reliability and meet the minimum denominator criteria, points would be assigned as follows: 1 point to those contracts that score in the top third of all contracts, 0 points to those that score in the middle third of all contracts, and 1 negative point to those that score in the bottom third of all contracts.
Step 5	For each contract, the HEI would be calculated as the weighted average of the points assigned in Step 4 using the Star Ratings measure weights and including only measures for which the contract met all inclusion criteria.

The HEI would be calculated separately for the overall and summary ratings, as proposed at §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi), since the set of included measures differs for the overall, Part C summary, and Part D summary ratings. Four types of health equity indices would be calculated, with up to three health equity indices for each contract, as applicable, one for the overall rating for MA–PDs; the Part C summary rating for MA-only, MA–PD, and cost contracts; the Part D summary rating for MA–PD and cost contracts; and the Part D summary rating for PDP (that is standalone Part D) contracts. The HEI calculated for the overall rating would be based on all of the Part C and Part D measures that meet the inclusion criteria for the HEI for each MA–PD contract. The HEI for the Part C summary rating would include all of the Part C measures that meet the inclusion criteria for the HEI for the contract. The HEI for the Part D summary rating would be calculated separately for MA–PD (including cost) and PDP contracts and would include all of the Part D measures that meet the inclusion criteria for the HEI for the contract.

In order to qualify for an HEI reward, we propose at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) that contracts must have a minimum rating-specific HEI score of greater than zero. We also propose a tiered HEI reward structure based on the percentage of enrollees in each contract who have the specified SRFs. Requiring both a minimum HEI score and a minimum percentage of enrollees in a contract with the

specified SRFs is intended to avoid rewarding contracts that serve very few enrollees with the specified SRFs or do not perform well among enrollees with the specified SRFs relative to other contracts. This proposed HEI reward structure supports our goals for the HEI reward in that it avoids rewarding contracts that do not serve many enrollees with SRFs included in the HEI, making it easier for them to do well, and encourages MA, cost, and PDP contracts to enroll individuals with SRFs.

We propose that contracts that have percentages of enrollees with any of the specified SRFs in a given year that are greater than or equal to one-half of the contract-level median percentage of enrollees with the specified SRFs up to, but not including, the contract-level median would qualify for one-half of the HEI reward. Contracts that have percentages of enrollees with any of the specified SRFs greater than or equal to the contract-level median would qualify for the full HEI reward. Table 6 is a high-level summary of how the HEI score is converted into the HEI reward.

TABLE 6: CONVERTING HEI SCORE INTO HEI REWARD

Percentage of Enrollees with Specified SRFs Threshold	Amount of Reward
% of enrollees in a contract with the specified SRFs < 0.5 of the median for all contracts.	Zero Reward.
% of enrollees in a contract with the specified SRFs ≥ 0.5 of the median for all contracts and < the median for all contracts.	HEI reward would vary from 0 to 0.2 on a linear scale for contracts that have an HEI score > 0.
% of enrollees in a contract with the specified SRFs ≥ the median for all contracts.	HEI reward would vary from 0 to 0.4 on a linear scale for contracts that have an HEI score > 0.

We are also considering an alternative non-tiered HEI reward structure, where all contracts with percentages of enrollees with any of the specified SRF greater than or equal to one-half of the contract-level median would qualify for the full HEI reward. Both the tiered and non-tiered HEI reward structures align with our goals of promoting enrollment of enrollees with SRFs and not rewarding contracts that may do well among enrollees with SRFs but serve very few enrollees in this population, although the tiered HEI reward structure goes further in aligning with these goals. The non-tiered HEI reward structure aligns better with the goal of ease of use and understanding for contracts and other stakeholders.

We propose at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) that the contract percentages of enrollees with SRFs included in the HEI would be based on enrollment in the most recent of the 2 years of data used to calculate the HEI. For example, if the HEI includes data from measurement years 2024 and 2025, enrollment would be from 2025. We recognize D–SNP only contracts would meet the enrollment thresholds under either the tiered or non-tiered HEI reward structure; however, other plans that do not initially meet the thresholds can also work to increase enrollment of people with SRFs to meet the enrollment thresholds, which aligns with the goal of promoting enrollment of enrollees with SRFs. D–SNP only contracts would also need to perform sufficiently well among enrollees with the specified SRFs to qualify for a reward based on the HEI. One consideration in developing the proposed thresholds for the minimum percentages of enrollees with SRFs included in the HEI needed to qualify for an HEI reward is that higher thresholds could potentially create geographic barriers in certain parts of the country to qualifying for the HEI reward because there is variation by State in the percent of enrollees who are LIS/DE or disabled. Both the tiered HEI reward and non-tiered HEI reward structures account for this as all states have percentages of LIS/DE/disabled enrollees that are greater than one-half the contract-level median based on 2019 data, although the non-tiered structure goes further in addressing this concern, as many states do not have percentages of LIS/DE/disabled enrollees that are greater than the contract-level median. As specified at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) the contract-level median and half of the contract-level median would be calculated and assessed separately for MA and standalone Part D (that is, PDP) contracts.

Because enrollees in Puerto Rico are not eligible for LIS, we believe that a different approach is necessary for contracts with services areas wholly located in Puerto Rico. We propose at §§ 422.166(f)(3)(vii)(A) and (B) and 423.186(f)(3)(vii)(A) and (B) to use a modified calculation to determine the percentage of enrollees with SRFs included in the HEI for contracts with service areas wholly located in Puerto Rico. We propose to limit this treatment to contracts with service areas wholly in Puerto Rico because our analysis indicates that for plans with services areas that include Puerto Rico and other locations, only a small portion of the enrollment is in Puerto Rico. We propose to estimate the number of enrollees with the specified SRFs in these contracts differently. We would start with the percentage of DE/disabled enrollees calculated from administrative data, and then add the estimated percentage LIS by taking the LIS/DE percentage calculated for the CAI for contracts with service areas wholly in Puerto Rico at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees. We need to estimate the number of LIS enrollees because LIS is not available in Puerto Rico; we are using the estimated LIS/DE information from the CAI calculations since these

are the only data available on the estimated percentage of enrollees in Puerto Rico contracts that would qualify for LIS. We would then add the estimated LIS percentage to the DE/disabled percentage calculated from administrative data to get the LIS/DE/disabled percentage of enrollees in Puerto Rico. This calculation could result in a slight overestimate since some disabled enrollees may also be captured in the estimated LIS percentage; therefore, contracts with service areas wholly in Puerto Rico would be excluded from our calculations to determine one-half of the contract-level median and the contract-level median of enrollees with SRFs included in the HEI. We believe that this approach would ensure equitable treatment of contracts with service areas outside of Puerto Rico. In our simulations of the HEI, we found that the slight overestimate had little impact on whether contracts with service areas wholly in Puerto Rico met the one-half of the contract-level median or contract-level median thresholds.

We also propose that contracts would need to have an HEI score greater than zero on the HEI calculated for the given rating (overall or summary rating) to qualify for a reward for that rating. As specified at proposed §§ 422.166(f)(3)(i) and 423.186(f)(3)(i), the HEI score for the overall rating would include the applicable Part C and D measures, the HEI score for the Part C summary rating would include only the applicable Part C measures, and the HEI score for the Part D summary rating would include only the applicable Part D measures. An HEI score of greater than zero means that the contract on average scored in the middle third or better across measures included in the HEI for enrollees with the SRF(s). HEI scores closer to 1.0 indicate better performance for enrollees with the SRFs included in the HEI. While we are initially proposing to require a minimum HEI score of greater than zero for contracts to receive an HEI reward, we may consider increasing this minimum score over time to continue to encourage improved contract performance for enrollees with SRFs included in the HEI. Any such increase to the minimum HEI score would be proposed through subsequent notice-and-comment rulemaking.

We propose at §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii) that the HEI reward would vary from 0 to 0.4 on a linear scale for contracts that meet the threshold for the median percentage of enrollees with SRFs included in the HEI, with a contract receiving 0 reward if the contract received a score of 0 or less on the HEI and a 0.4 reward if the contract received a score of 1 on the HEI. Similarly, the HEI reward would vary from 0 to 0.2 on a linear scale for contracts that meet the threshold for one-half of the contract-level median percentage of enrollees with SRFs included in the HEI, but do not meet or exceed the contract-level median percentage of enrollees with SRFs included in the HEI. Contracts that cannot have an HEI score calculated (that is, contracts that do not have reliable measure scores or do not meet the denominator criteria for at least half of the measures included in the HEI or contracts that do not have at least 500 enrollees) would not receive an HEI reward.

As an example, if a contract meets the contract-level median percentage of LIS/DE/disabled enrollees and receives an HEI score of 0.722325, this would translate on a linear scale to a reward of 0.288930. That is, the size of the HEI reward would equal 0.4 times the difference between the HEI score and the threshold, divided by the difference between the maximum HEI score and the threshold (0.4*(0.722325–0)/(1–0), which equals 0.288930). As another example, if a contract meets one-half the contract-level median percentage of LIS/DE/disabled enrollees but does not meet the contract-level median percentage of LIS/DE/disabled enrollees and receives an HEI score of 0.722325, this would translate on a linear scale to a reward of 0.144465. That is, the size of the HEI reward would equal 0.2 times the difference between the HEI score and the threshold, divided by the difference between the maximum HEI score and the threshold (0.2*(0.722325–0)/(1–0), which equals 0.144465). The HEI reward would be rounded and displayed with 6 decimal places similar to how the CAI values are displayed.

As proposed at §§ 422.166(f)(3)(ix) and 423.186(f)(3)(ix), once each of the HEI rewards are calculated, the applicable HEI reward would be added to the unrounded overall and Part C and D summary ratings after the addition of the CAI and the application of the improvement measures described in §§ 422.166(g)(1) and 423.186(g)(1) and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star. For example, if the HEI reward was 0.288930, as previously described in the example, and the unrounded overall rating was 4.234210 after the addition of the CAI and the application of the improvement measure hold harmless rule, the unrounded overall rating would be 4.523140 (4.234210 + 0.288930) resulting in a final, rounded overall rating of 4.5.

We also propose changes in the following sections to revise references to the existing reward factor or to limit application of the current reward factor to the Star Ratings through the 2026 Star Ratings: §§ 422.166(c)(1), 422.166(d)(1) 422.166(f)(1), 422.166(f)(2)(i), 422.166(g)(1), 423.186(c)(1), 423.186(d)(1) 423.186(f)(1), 423.186(f)(2)(i), and 423.186(g)(1). The new HEI reward would be implemented for the 2027 Star Ratings covering primarily the 2024 and 2025 measurement years. The existing reward factor would continue to be calculated through the 2026 Star Ratings.

We simulated the impact of removing the current reward factor and adding the proposed HEI reward. In simulations using data from the 2020 and 2021 Star Ratings,[199] the median percentage of LIS, DE, and disabled enrollees was 41.645 percent and one-half the median was 20.822 percent for MA and cost contracts. Half of MA and cost contracts were at or above the median, 33 percent were at or above one-half the median up to but not including the median, and 17 percent were below one-half the median. In the simulations, 88 percent of MA–PD contracts that received an overall rating received an HEI score, 42 percent received an HEI score greater than zero, and 34 percent received an HEI reward. The range of HEI scores among MA–PD contracts for the overall rating was –0.888889 to 1.000000. The average reward for the overall rating among MA–PD contracts with an HEI score greater than zero was 0.109. When simulating the removal of the current reward factor and addition of the proposed new HEI reward, 7 (1.7 percent) MA–PD contracts gained one-half star on the overall rating and 54 (13.4 percent) MA–PD contracts lost one-half star on the overall rating compared to the 2021 Star Ratings. Among PDP contracts, the median percentage of LIS, DE, and disabled enrollees was 13.848 percent and one-half the median was 6.924 percent. Fifty-one percent of PDP contracts were at or above the median, 39 percent were at or above one-half the median up to but not including the median, and eleven percent were below one-half the median. Among PDP contracts that received a Part D Summary Star Rating, 91 percent received an HEI score, 47 percent received an HEI score greater than zero, and 40 percent received an

[199] Since data collections for HEDIS and CAHPS were curtailed for the 2021 Star Ratings due to the COVID–19 pandemic (CMS–1755–IFC), these simulations used HEDIS and CAHPS measure data from the 2019 and 2020 Star Ratings.

HEI reward. The range of HEI scores among PDP contracts was –1.000000 to 1.000000. The average reward among PDP contracts with an HEI score greater than zero was 0.160. Compared to the 2021 Star Ratings, 3 (5.3 percent) PDP contracts gained one-half star on the Part D Summary Rating and 7 (12.3 percent) PDP contracts lost one-half star on the Part D Summary Rating.

We solicit comment on these proposals.

H. Improvement Measure Hold Harmless (§§ 422.166(g)(1) and 423.186(g)(1))

In the April 2018 final rule, we discussed that one of the goals of the Part C and Part D Star Ratings program is to drive quality improvement for plans and providers (83 FR 16521). In that final rule, CMS adopted, at §§ 422.166(g)(1) and 423.186(g)(1), a hold harmless provision for the inclusion of the Part C and/or Part D improvement measures for contracts with 4 or more stars for the highest rating. Under this provision, the highest rating is calculated both with and without the improvement measures; contracts with 4 or more stars without including the improvement measures are held harmless from having the highest rating reduced by the addition of the improvement measures. The original intent of this hold harmless provision was to recognize that higher performing contracts have less room to improve (83 FR 16578).

Our experience with the Part C and Part D Star Ratings program since this policy was finalized suggests that contracts with 4 or 4.5 stars for their highest rating still have room for improvement. For example, based on a review of data from the 2020 Star Ratings, MA–PD contracts with 4 stars for the overall rating received 5 stars on 42 percent of measures on average, those with 4.5 stars for the overall rating received 5 stars on 55 percent of measures on average, and those with 5 stars for the overall rating received 5 stars on 79 percent of measures on average. PDP contracts with 4 stars for the Part D summary rating received 5 stars on 26 percent of measures on average, those with 4.5 stars for the Part D summary rating received 5 stars on 28 percent of measures on average, and those with 5 stars for the Part D summary rating received 5 stars on 57 percent of measures on average.

We believe that the hold harmless provision for the highest rating is not needed for 4 and 4.5 star contracts because they still have the potential to increase scores across measures and thus their Star Ratings. In order to encourage continued improvement across all measures for contracts with 4 and 4.5 stars for their highest rating, we propose to modify § 422.166 at paragraphs (g)(1)(i) and (ii) and § 423.186 at paragraphs (g)(1)(i) and (ii) to apply the improvement measure hold harmless provision to only contracts with 5 stars for their highest rating beginning with the 2026 Star Ratings.

We welcome feedback on this proposal.

I. Extreme and Uncontrollable Circumstances (§§ 422.166(i) and 423.186(i))

1. 60 Percent Rule

Currently, the Star Rating for each non-CAHPS measure score is determined by applying a clustering algorithm to the numeric value scores from all contracts required to submit the measure. The cut points for non-CAHPS measures are derived from this clustering algorithm. As discussed in the April 2019 final rule and described at §§ 422.166(i)(9), 422.166(i)(10), 423.186(i)(7), and 423.186(i)(8), we exclude from this clustering algorithm and from the reward factor calculations (under §§ 422.166(f)(1) and 423.186(f)(1)) the numeric values for affected contracts with 60 percent or more of their enrollees in Federal Emergency Management Agency (FEMA) designated Individual Assistance areas at the time of an extreme and uncontrollable circumstance (84 FR 15776–15777). Affected contracts are contracts that meet all of the criteria in §§ 422.166(i)(1) and 423.166(i)(1). We generally call this the ''60 percent rule'' to distinguish it from the adjustments provided under §§ 422.166(i) and 423.186(i) for affected contracts with 25 percent of their enrollment residing in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

This exclusion ensures that any impact of the extreme and uncontrollable circumstance on certain affected contracts' measure-level scores does not have an impact on the cut points or reward factor for other contracts. When this rule was first implemented, the concern was that a contract impacted by an extreme and uncontrollable circumstance would have significantly different scores than other contracts and that these significantly different scores would shift the cut points and/or reward factor thresholds for non-affected contracts. Our analyses since the rule was implemented show the measure scores for affected contracts do not tend to be outliers and that this 60 percent rule can have adverse effects when extreme and uncontrollable circumstances affect nearly all contracts, as we saw with the COVID–19 PHE.

We are proposing to limit to the 2025 and earlier Star Ratings, application of the rule at §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) that excludes numeric values for affected contracts with 60 percent of their enrollees residing in FEMA-designated Individual Assistance areas at the time of an extreme and uncontrollable circumstance from cut point calculations and reward factor determinations. During the COVID–19 pandemic, we adopted a change to remove these rules temporarily since all contracts qualified for the extreme and uncontrollable circumstances policy as a result of COVID–19 in 2020; this change was adopted in the interim final rule titled ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' which appeared in the **Federal Register** and effective on September 2, 2020, and the final rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; etc.'' which appeared in the **Federal Register** on May 9, 2022 and effective on June 28, 2022 (hereinafter referred to as the May 2022 final rule). The removal of the 60 percent rule was necessary to calculate measure stars for most measures for the 2022 Star Ratings and for HEDIS measures that are based on the Health Outcomes Survey (HOS) (HEDIS–HOS measures) for the 2023 Star Ratings. Without the removal of the rule, CMS would not have been able to calculate stars for most measures for 2022 Star Ratings and for the HEDIS–HOS measures for the 2023 Star Ratings because all contracts qualified for the extreme and uncontrollable circumstances policy as a result of COVID–19 in 2020.

Beginning with the 2024 Star Ratings, measure scores that are extreme outliers will be removed through Tukey outlier deletion, a standard statistical method to remove extreme outliers, as codified at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), prior to applying the clustering methodology to determine the cut points. The combination of mean

resampling (implemented with the 2022 Star Ratings and described at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i)) and Tukey outlier deletion will alleviate the impact of any extreme outliers. Thus, if a contract is impacted by an extreme and uncontrollable circumstance and as a result has a significantly lower score on a measure, the score would be removed if it is an extreme outlier. Removing extreme outliers will eliminate the concern that other contracts are inappropriately impacted by changes in scores for contracts impacted by disasters. By removing the 60 percent rule, we will also simplify the Star Ratings calculations and continue to allow measure-level Star Ratings to be calculated if all or most contracts qualify for an extreme or uncontrollable circumstance in the future.

We are proposing to amend sections §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) to remove the 60 percent rule beginning with the 2026 Star Ratings for non-CAHPS measures, including the Health Outcomes Survey measures even though the measurement period is slightly different for these measures. We welcome comments on this proposal.

2. Health Outcomes Survey (HOS) Measures

We adopted regulations for how Star Ratings would be calculated in the event of extreme and uncontrollable circumstances in the April 2019 final rule. We explained in the April 2019 final rule (CMS–4185–F) that for most measures, the extreme and uncontrollable circumstance adjustment applies for disasters from 2 years prior to the Star Ratings year (that is, a disaster that begins [200] during the 2020 measurement period results in a disaster adjustment for the 2022 Star Ratings). For Part C measures derived from HOS, the disaster adjustment is delayed an additional year due to the timing of the survey and 1 year recall period. That is, for measures derived from the HOS, the disaster policy adjustment is for 3 years after the extreme and uncontrollable circumstance. For example, we noted at 84 FR 15772–15773 that the 2023 Star Ratings would adjust measures derived from the HOS for 2020 extreme and uncontrollable circumstances. We are proposing to clarify in § 422.166(i)(3)(iv) the timing for HOS measure adjustments for extreme and uncontrollable circumstances. We welcome comments on this proposal.

J. Quality Bonus Payment Rules (§ 422.260)

Sections 1853(n) and 1853(o) of the Act require CMS to make QBPs to MA organizations that achieve at least 4 stars in a 5-star quality rating system. In addition, section 1854(b)(1)(C) of the Act ties the share of savings that MA organizations must provide to enrollees as the beneficiary rebate to the level of an MA organization's QBP rating. The administrative review process for a MA contract to appeal their QBP status is laid out at § 422.260(c). As described in the final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes,'' which was published in the **Federal Register** on April 15, 2011 (76 FR 21490–91), §§ 422.260(c)(1) and (2) create a two-step administrative review process that includes a request for reconsideration and a request for an informal hearing on the record, and § 422.260(c)(3) imposes limits on the scope of requests for an administrative review. Historically, every November CMS has released the preliminary QBP ratings for MA contracts to review their ratings and to submit an appeal request under § 422.260(c) if they believe there is a calculation error or incorrect data are used. We propose to clarify in § 422.260(c)(3)(iii) some additional aspects of that administrative review process for appeals of QBP status determinations. These clarifications are how we have historically administered the appeals process so we are not proposing changes to how the appeals process has previously been administered.

When an MA organization requests an administrative review of its QBP status, permissible bases for these requests include a calculation error (miscalculation) or a data inaccuracy (incorrect data). A calculation error could impact an individual measure's value or the overall Star Rating. Historically, if an MA organization believes the wrong set of data was used in a measure (that is, following a different timeframe than the one in the measure specifications as adopted in the applicable final rule), this is considered a calculation error.

Currently, § 422.260(c)(3)(i) provides that CMS may limit the measures or bases for which an MA organization may request an administrative review. As described in 76 FR 21490, the appeals process is limited to data sets that have not been previously subject to independent validation. We propose to add a new paragraph in § 422.260(c)(3)(iii) to clarify that certain data sources would not be eligible for requesting an administrative review. We are proposing to clarify at § 422.260(c)(3)(iii) that an administrative review cannot be requested based on data accuracy for the following data sources: HEDIS, CAHPS, HOS, Part C and D Reporting Requirements, PDE, Medicare Plan Finder pricing files, data from the Medicare Beneficiary Database Suite of Systems, MARx system, and other Federal data sources. The listed data sources have either already been validated or audited or come from the CMS system of record for that type of data such as enrollment data, which make it inappropriate to use the QBP appeal process to challenge the accuracy of the data. For example, HEDIS measures and measures collected through the Part C and D reporting requirements have previously been audited or validated for accuracy; NCQA has a formal audit process for all HEDIS measures to check for accuracy, and MA plans sign off on the accuracy of the data following the audit and prior to the data being submitted to CMS. Similarly, data from the Part C and D reporting requirements are validated through an independent contractor (see 42 CFR 422.516(g) and § 423.514(j)) before the data are submitted by MA organizations and Part D plan sponsors to CMS and used for Star Ratings measures. (With regard to Part D data and measures, the MA organization offering an MA–PD must comply with the applicable Part D regulations under § 422.500.) Because the MA organization bears the responsibility of data accuracy as well as signs off on audit findings in these situations, it is inappropriate to use the QBP appeal process to challenge the accuracy of these data. Organizations would have ample opportunity to raise any concerns about these data prior to submission to CMS for use in the Star Ratings.

We are also proposing that MA organizations cannot appeal measures that are based on feedback or surveys that come directly from plan enrollees. Measures derived from CAHPS and HOS data are not appealable because plans cannot challenge the validity of an enrollee's response since that is the enrollee's perspective. MA and PDP contracts contract with the CMS-approved vendor of their choice to conduct CAHPS and HOS, and these independent survey vendors conduct the surveys for contracts using detailed specifications provided by CMS and in some cases contract-specific information

[200] We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

such as telephone numbers and language preference information provided directly by the MA and PDP contract. There are detailed specifications for data collection [201] for vendors to follow; CMS conducts oversight of the data collection efforts of the approved survey vendors.

Measures derived from Prescription Drug Event (PDE) data, Medicare Beneficiary Database Suite of Systems, enrollment data from Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources (for example, FEMA disaster designations) also cannot be appealed for data accuracy because we are pulling data from the system of record or authoritative data source. Part D sponsors submit PDE to CMS via the Drug Data Processing Systems (DDPS), which processes and validates the data. Sponsors must meet the PDE submission deadline to be included in the annual Part D payment reconciliation, and sponsors must certify the claims data (42 CFR 423.505(k)(3)). As another example, enrollment data used in the Star Ratings are also used for the monthly payment of contracts and any discrepancies would have been resolved through retroactive adjustments as needed. Similarly, Medicare Plan Finder (MPF) pricing files cannot be appealed. Plans use the Health Plan Management System (HPMS) Part D Pricing File Submission (PDPFS) module to submit their drug pricing and pharmacy data for posting on the MPF. After the data are submitted, CMS performs a multi-step validation. Validation results are provided to sponsors to correct their data or to attest to the accuracy of the data prior to display on MPF. Part D sponsors are required to perform their own quality assurance checks before submission to ensure that the files are complete and accurate.[202]

Further, in conducting the reconsideration under § 422.260(c), the reconsideration official reviews the QBP determination, the evidence and findings upon which it was based, and any other written evidence submitted by the organization or by CMS before the reconsideration determination is made. Currently, § 422.260(c)(1)(i) provides that the request for reconsideration must specify the given measure(s) in question and the basis for the MA organization's reconsideration request; the alleged error could impact a measure-level score or Star Rating, or the overall Star Rating. The request must include the specific findings or issues with which the MA organization disagrees and the reason for the disagreement, as well as any additional evidence that the MA organization would like the reconsideration official to consider, as the basis for reconsideration. Currently, § 422.260(c)(2)(v) provides that the MA organization must provide clear and convincing evidence that CMS's calculations of the measure(s) and value(s) in question were incorrect; in other words, the burden is on the MA organization to prove an error was made in the calculation of their QBP rating. We are proposing to revise this standard to require the MA organization to prove by a preponderance of evidence that CMS's calculations of the measure(s) and value(s) in question were incorrect and to add additional language at § 422.260(c)(2)(v) clarifying that the burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status. We believe that the appropriate standard of proof is the preponderance of the evidence.

If the hearing officer's decision is in favor of the MA organization, the MA organization's QBP status is recalculated using the corrected data and applying the rules at §§ 422.160 through 422.166. Under our current implementation of § 422.260, recalculation could cause the requesting MA organization's QBP rating to go higher or lower. In some instances, the recalculation may not result in the Star Rating rising above the cut-off for the higher QBP rating. We are proposing additional language at § 422.260(c)(1)(i) to clarify that ratings can go up, stay the same, or go down based on an appeal of the QBP determination.

Under § 422.260(d), CMS may revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year on the basis of any credible information, including information provided during the administrative review process, requested by a different MA organization, that demonstrates that the initial QBP determination was incorrect. CMS issues annual guidance to MA organizations about the QBP appeal process available under § 422.260 each November titled, for example, ''Quality Bonus Payment Determinations and Administrative Review Process for Quality Bonus Payments and Rebate Retention Allowances.'' We interpret and implement § 422.260 through this guidance and our administration of the annual administrative review process.

When the reconsideration official or hearing officer's decision for a particular appeal or other credible information suggests that there was a systematic error impacting all or a subset of contracts, the QBP status of all contracts is re-calculated using the corrected data and applying the rules at §§ 422.160 through 422.166. If the re-calculated QBP rating for a contract other than the appealing contract results in a lower rating, the original preliminary QBP rating will be used. Thus, a contract's QBP rating will not be decreased by CMS as a result of a systematic re-calculation for the current Star Ratings and associated QBP year to correct a systematic calculation error; however, the issue identified will be addressed in the next year's Star Ratings. However, if the QBP rating is higher for a contract after the systematic re-calculation, the new rating will be used. For example, if CMS has to do a systematic re-calculation for the 2023 Star Ratings following the release of the preliminary 2024 QBP ratings, a contract's 2023 Star Ratings used for the 2024 QBP ratings will not be decreased but the change that caused a systematic recalculation will be addressed when the 2024 Star Ratings are calculated. If the re-calculation of the 2023 Star Ratings results in a higher rating for a contract, the higher rating will be used. We propose to add language at § 422.260(d) to clarify that a reopening of a QBP determination to address a systemic calculation issue that impacts more than the MA organization that submitted an appeal would only be updated if it results in a higher QBP rating for other MA organizations that did not appeal. This is how we have historically noted how we would handle this type of systemic calculation error as described in our annual HPMS memo released in November each year.

We welcome comments on this proposal.

K. Calculation of Star Ratings (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i))

In the June 2020 final rule, we finalized use of Tukey outlier deletion effective for the Star Ratings issued in October 2023 and subsequent years. (85 FR 33833–36) In the rulemakings since that time, we have not proposed to eliminate the Tukey outlier deletion aspect of the Star Ratings methodology.

[201] MA and PDP CAHPS Survey administration protocols are contained in the *MA & PDP CAHPS Survey Quality Assurance Protocols & Technical Specifications* and are available at *https://ma-pdpcahps.org/en/quality-assurance/*. The *HOS Quality Assurance Guidelines and Technical Specifications* manual details the requirements, protocols, and procedures for the HOS administration and are available at *https://www.hosonline.org/en/program-overview/survey-administration/*.

[202] See May 28, 2021 HPMS memorandum, Contract Year (CY) 2022 Part D Pricing Data Submission Guidance. *https://www.cms.gov/files/document/cy2022drugpricingsubmissionguidelines05282021final.pdf*

As we stated in May 2022 final rule (87 FR 27766), we will implement Tukey outlier deletion beginning with the 2024 Star Ratings to help improve stability of cut points and prevent cut points from being influenced by outliers. We further stated that with Tukey outlier deletion, extreme outliers will be removed from measure scores prior to clustering to prevent outliers from impacting cut points for all contracts. However, it appears that the sentence in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) (''Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed.'') was inadvertently removed from the codified regulation text. We are proposing a technical amendment to fix this codification error from the May 2022 final rule. In addition, although the provision regarding application of the Tukey outlier deletion policy was originally at the end of paragraph (a)(2)(i) in each regulation, we are also proposing a non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) since Tukey outlier deletion is applied prior to the other steps. We believe that this makes the regulation text clearer.

We welcome comment on this proposal.

VI. Updates to Programs of All-Inclusive Care for the Elderly (PACE) Policy

A. Contract Year Definition (§ 460.6)

Sections 1894(a)(9) and 1934(a)(9) of the Act define the trial period for PACE organizations as the first 3 contract years operating a PACE program under a PACE program agreement. Sections 1894(e)(4) and 1934(e)(4) of the Act require CMS, in cooperation with the State administering agency, to conduct a comprehensive annual review of the PACE organization's operation of the PACE program during the trial period to assure compliance with all significant requirements. The rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)'', which appeared in the November 24, 1999 issue of the **Federal Register** (64 FR 66234) (hereinafter referred to as the 1999 PACE interim final rule) defined a contract year at § 460.6 as the term of the PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, as determined by CMS. This enables CMS to adjust the length of the initial contract year so that it always ends on December 31 and subsequent contract years align with a standard annual calendar year consisting of 12 months (64 FR 66236). For example, for a PACE organization that signs a program agreement in March 2022, CMS would extend the organization's initial contract year through December 31, 2023, so that all future contract years would align with calendar years.

As previously stated, CMS is required to conduct comprehensive reviews during a PACE organization's trial period to assess all significant regulatory requirements, and these reviews must be conducted on an annual basis for the first 3 contract years. Currently the first trial period contract year may include up to 23 months, but the subsequent two trial period contract years are limited to 12 months, each beginning on January 1 and ending on December 31. CMS has developed audit protocols to comprehensively assess PACE organizations which require the availability of multiple months of program data and typically take 6 to 9 months to complete, including pre-audit data collection, audit fieldwork, and the corrective action period which allows time for PACE organizations to correct deficiencies identified during audits. CMS must conduct the first trial period audit within the first contract year in order to comply with the statutory and regulatory requirements. However, our ability to schedule and conduct the first trial period audit is limited by when a PACE organization enters into a program agreement, the current contract year definition in § 460.6, and when the PACE organization begins enrolling participants during their first contract year. Depending on when the program agreement is signed, the first trial period audit may be required within 12 months from the contract start date which we believe is not a sufficient length of time for new PACE organizations to establish their operations before undergoing an audit.

In order to have enough data to conduct a comprehensive audit, CMS has found it necessary to allow a PACE organization to operate with enrollees for at least 6 months before conducting its first trial period audit, which may not occur until the latter half or end of their first contract year. However, unless the first trial period audit is scheduled early in the calendar year, we encounter significant operational challenges conducting subsequent audits for the second and third years of the trial period in accordance with statutory and regulatory requirements, while still giving PACE organizations sufficient time between audits to ensure they are able to fully correct the deficiencies identified during an audit before CMS collects data for the next audit. Specifically, delaying the first trial period audit until later in the calendar year to ensure adequate PACE organization operational experience, reduces the time between audits, which creates overlap between timeframes to correct deficiencies and the data collection period for subsequent trial period audits. For example, under the current contract year definition, a PACE organization that enters into a program agreement on January 1, 2023 must receive its first comprehensive trial period audit by December 31, 2023, its second trial period audit in 2024, and its third trial period audit in 2025. If CMS first audits the PACE organization in early 2023, we would not have enough data to conduct a comprehensive review. However, waiting to schedule the first audit until later in 2023 reduces the timeframe within which CMS can schedule the second and third trial year audits required in 2024 and 2025. Given that a PACE organization may need 9 months to complete the first trial period audit initiated in 2023, and multiple months of data are required for each audit, it is operationally challenging for CMS to schedule and complete the next 2 annual audits within the trial period while still affording PACE organizations a sufficient amount of time between audits to correct identified deficiencies.

CMS therefore proposes to amend the definition of contract year at § 460.6 to state that a PACE organization's initial contract year may be 19 to 30 months, as determined by CMS, but in any event will end on December 31. Under the proposed contract year definition, although the duration of the initial contract year of the trial period would change, the initial contract year would continue to begin when the program agreement is signed and end on December 31 to ensure subsequent contract years follow the standard annual calendar year cycle. For PACE organizations with an initial contract year start date of January 1 through June 1, CMS would extend the initial contract year through the following year. For example, for a program agreement signed on January 1, 2024 or up until June 1, 2024, the initial contract year would end December 31, 2025. The second and third contract years would begin on January 1, 2026 and January 1, 2027, respectively. Additionally, for PACE organizations with an initial contract year start date of July 1 through December 1, CMS would

extend the initial contract year through the second succeeding year. For example, for a program agreement signed on July 1, 2024, the initial contract year would end December 31, 2026. The second and third contract years would begin on January 1, 2027 and January 1, 2028, respectively. This would allow CMS to continue adjusting the length of the initial contract year so that subsequent contract years align with the calendar year, but it would provide greater flexibility around scheduling the first trial period audit. We believe that making the minimum length of time 19 months (as opposed to 12 months) would ensure organizations have sufficient time both to enroll participants and gain adequate program experience before their initial audit, while still allowing time to address deficiencies and implement improvements before engaging in another audit. In addition, this change would enable CMS to conduct the first trial period audit early enough in a calendar year that it does not adversely impact the second and third trial period audits. While we anticipate that this modification would allow us more flexibility in scheduling the first trial period audit, we intend to maintain our commitment to conducting first contract year audits as expeditiously as possible. For example, if a contract were signed on January 1, 2024, the initial contact year would extend to December 31, 2025 and CMS could potentially schedule the first trial period audit early in the 2025 calendar year. This would ensure that the PACE organization has sufficient time to operate before the start of the data collection period for the first trial period audit, and it would still allow CMS operational flexibility in scheduling the next two audits in 2026 and 2027.

We solicit comment on whether CMS should consider a different timeframe for the initial contract year. Specifically, we are seeking feedback on whether CMS should consider defining the initial contract year as 25 to 36 months to allow organizations additional time to implement and operate a PACE program before undergoing their first audit.

Since the effect of the proposed change would be to provide CMS with more flexibility when scheduling initial trial period audits without placing new requirements on CMS or PACE organizations, we believe this change would create no additional burden for PACE organizations. Additionally, we do not expect this change to have economic impact on the Medicare Trust Fund.

B. Determining That a Substantially Incomplete Application Is a Nonapplication (§§ 460.12 and 460.20)

Sections 1894(e)(8) and 1934(e)(8) of the Act established CMS' authority regarding PACE provider application requirements. Based on this authority, we are proposing to strengthen the PACE regulations at §§ 460.12(a) and (b) and 460.20(b), which pertain to application requirements, by further defining what constitutes a complete and valid application.

CMS accepts PACE applications from entities seeking to establish a PACE program (initial applicants) or to expand an existing PACE program's service area (including both expansion of a PACE programs' geographic service area and/or the addition of a new PACE center), on designated quarterly submission dates.

In order to receive funds under Part D to provide prescription drug benefits, PACE organizations must qualify as Part D sponsors under *§* 423.502(c)(1) by submitting an application in the form and manner required by CMS. Therefore, as a matter of necessity, initial PACE applicants that provide the Part D benefit to eligible beneficiaries must submit a separate Part D application. Effective March 31, 2017, CMS requires organizations to submit all applications electronically via the Health Plan Management System (HPMS). The PACE application includes attestations and certain required documents to ensure compliance with established PACE regulations, including but not limited to: policies and procedures related to enrollment, disenrollment, grievances and appeals; information regarding the legal entity and organizational structure; and State-based documents, including a State assurances document. The State assurances document is a template that includes standard statements regarding the State's roles and responsibilities and includes the physical address of the proposed PACE center, geographic service area, or both, as applicable, depending on the type of application. This document must be signed by an official within the applicable State Administering Agency (SAA), the designated agency for the PACE program in the State in which the program is to be located, and serves as confirmation of the State's support for the application. It is imperative that the applicant demonstrate the State's support as part of the application since the State is a party to the PACE program agreement, which, once approved and finalized, is a 3-way contract between CMS, the State, and the PACE organization.

Section 460.12 sets forth the application requirements for an organization that wishes to qualify as a PACE organization, and for an active PACE organization that seeks to expand its geographic service area and/or add a new PACE center site. Paragraph (a) of § 460.12 states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area and/or add a new center site must submit a complete application to CMS in the form and manner specified by CMS. Furthermore, § 460.12(b)(1) specifies that an entity's application to become a PACE organization must include an assurance from the SAA of the State in which the program is to be located indicating that the State considers the entity qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity. Similarly, an existing PACE organization's application to expand its service area and/or add a PACE center site must include an assurance from the SAA of the State in which the program is located indicating that the State is willing to amend the signed PACE program agreement to include the expanded service area and/or new center site (§ 460.12(b)(2)).

We indicated in the final rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)'', which appeared in the June 3, 2019 issue of the **Federal Register** (84 FR 25610) (hereinafter referred to as the June 2019 final rule) that applications received without the required State assurances document would not be considered a complete application and would therefore, not be reviewed (see 84 FR 25615 and 25671).

Section 460.20(a) provides that within 90 days, or 45 days in the case of an application to expand a service area or add a PACE center, after an entity submits a complete application to CMS, CMS takes one of the following actions in the form and manner specified by CMS: (1) approves the application or (2) denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial. An application is considered complete only when CMS receives all information necessary to make a determination regarding approval or denial (§ 460.20(b)).

As part of annual training sessions and resources available at: *https://www.cms.gov/Medicare/Health-Plans/PACE/Overview*, CMS has stated that the only required application document

that may not be available and submitted as part of the initial application submission on CMS' designated quarterly date is the State readiness review (SRR) of a center site, as applicable. The SRR is conducted by the State at the applicant's PACE center, and the accompanying report certifies that the PACE center satisfies all applicable local, State and Federal requirements and is ready for operations. CMS has instructed PACE applicants that this document may be uploaded when responding to a CMS request for additional information.

The application is not considered complete and valid without the required documentation from the applicable SAA that provides clear evidence of the State's support. However, in our experience, some PACE organizations submit a State assurances document that is not signed by the State, is provided after the designated submission date, or has changed the location of the proposed PACE center or included the corporate address as a placeholder. Should any of the aforementioned occur, the applicant is instructed to withdraw the application.

Under this proposal, we would treat any PACE application that does not include a signed and dated State assurances document that includes accurate service area information and the physical address of the PACE center as incomplete and invalid and therefore not subject to review or reconsideration. Entities that submit an application without a complete and valid State assurances document would have their application withdrawn from HPMS. They would then have to wait until the next quarterly submission date to submit the application with the State assurances included. We propose to add paragraph § 460.12(b)(3) to specify that any PACE application that does not include the proper State assurances documentation associated with the application would be considered incomplete and invalid.

In the June 2019 final rule, we added the phrase ''in the form and manner specified by CMS'' to § 460.12(a) when describing the submission to CMS of a complete application, to allow for submission of applications and supporting information in formats other than paper, which was the required format at the time the proposed rule was issued (84 FR 25671). We propose to amend § 460.12(a), which states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area (through a geographic service area expansion and/or addition of a new center site) must submit a complete application to CMS ''in the form and manner specified by CMS'' by adding a parenthetical with the words ''including timeframes for submission'' after ''manner'', in order to make clear that CMS will only accept applications that are submitted within the timeframes established by CMS.

We propose to establish at § 460.20(c) that any application that, upon submission, is determined to be incomplete under proposed § 460.12(b)(3) because it does not include a signed and dated State assurances document with accurate service area information and the physical address of the PACE center, as applicable, would be withdrawn by CMS, and the applicant would be notified accordingly. Proposed § 460.20(b)(1) would further specify that the applicant would not be entitled to a hearing if the application is withdrawn based on that determination. Without the necessary evidence of support for the application by the SAA, the application would not be valid and therefore not subject to reconsideration. We note this proposal would be consistent with how CMS addresses MA or Part D applicants that submit substantially incomplete applications. Such applications are considered invalid applications and applicant organizations are not entitled to a hearing per § 422.660 or § 423.650.

Finally, we are proposing to establish at § 460.12(a)(2) that an individual authorized to act for an entity that seeks to become a PACE organization (initial PACE applicant) is required to submit a separate Part D application that complies with the applicable requirements under Part 423 Subpart K. This is consistent with our current practice, under which initial PACE applicants must submit a Part D application. By contrast, existing PACE organizations seeking to expand their service area are not required to complete a Part D application. Therefore, consistent with our existing practice, we are not proposing to establish Part D application requirements for PACE organizations seeking to expand their existing service area. We also intend to continue our current practice of following the timeframes for PACE applications, including submission deadlines and review periods, for Part D applications associated with PACE applications—that is, we will continue to accept Part D applications from initial PACE applicants on a quarterly basis. We believe it is important to continue to align application and review and submission deadlines for PACE applicants to the extent practicable in order to promote consistency.

Consistent with current practice, we propose to treat an initial PACE application that does not include responsive materials for one or more sections of its Part D application as substantially incomplete, and those applications would not be reviewed or subject to reconsideration. Should this proposal be finalized, if the Part D application associated with an initial PACE application is deemed substantially incomplete, that would render the PACE application incomplete and therefore not subject to review or reconsideration.

C. PACE Past Performance (§§ 460.18 and 460.19)

Sections 1894(e)(4) and 1934(e)(4) of the Act establish CMS' authority to oversee the PACE program. To effectively oversee the PACE program, we are proposing to amend the PACE regulation at § 460.18 (CMS evaluation of applications) to incorporate an evaluation of past performance into the review of applications submitted by PACE organizations that seek to offer a PACE program or expand an approved program by adding a geographic service area and/or PACE center site or sites. Our evaluation of past performance would be a criterion CMS would use to review a PACE organization's application. The addition of this proposed evaluation criterion at § 460.18(c) would permit CMS to deny applications from PACE organizations based on the organization's past performance. Our past performance proposal takes into account any compliance letters received by an organization. We are also proposing to establish at § 460.18(d) that CMS may deny a PACE application if the PACE organization's agreement was terminated or not renewed during the 38 months preceding the date the application was first submitted to CMS.

The past performance of an organization is an important criterion for CMS to review when considering a PACE application because it provides valuable information about the ability of an organization to effectively operate a new program or expand an existing program. Organizations that have performed well are more likely to continue their high performance while organizations that have not may have difficulty meeting regulatory requirements in operating a new or expanded PACE program. This could pose a risk to the health and safety of the PACE participants they enroll. It is important for CMS to ensure that the legal entities with whom we hold

program agreements are able to appropriately provide services and benefits to PACE participants.

In the Medicare Advantage (MA) and Part D programs, CMS considers an organization's past performance during the evaluation of the application. We are modeling the PACE past performance proposal after the MA and Part D review regulations at 42 CFR parts 422 and 423, using applicable evaluation criteria in our proposal. We believe modeling the PACE past performance review criteria after the criteria that appear in the MA and Part D regulations is appropriate given that consideration of past performance has been a long-standing part of application reviews under the MA and Part D programs, resulting in the denial of applications of poor performing plans. CMS' goal is the same for PACE as it is in MA and Part D, which is to prohibit poor performing organizations from entering into new agreements, or expanding their service areas in the program.

In addition, we believe modeling past performance reviews in PACE on past performance reviews in MA and Part D is appropriate since PACE organizations that provide Part D benefits are subject to the regulations at 42 CFR 423, with the exception of those regulations CMS has waived in accordance with § 423.458(d). In addition, modeling after MA and Part D reduces burden by not having a different set of criteria for the non-Part D PACE benefits. In keeping with this requirement, our proposal would ensure that all entities that submit PACE applications would be subject to past performance reviews, the same as other entities that submit Part D applications.

In the January 2021 final rule (86 FR 5864), CMS established in regulation the methodology and criteria used to decide to deny an MA or Part D application based on prior contract performance (§ § 422.502(b) and 423.503(b)). We noted in the final rule that we 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 (86 FR 5999). In the January 2021 final rule and through subsequent rulemaking, CMS adopted the following factors as the bases for denying an MA or Part D application: (A) the organization was subject to an intermediate sanction; (B) the organization failed to maintain a fiscally sound operation; (C) the organization filed for bankruptcy or is under bankruptcy proceedings; (D) the organization had low Star Ratings for two or more consecutive years; or (E) the organization exceeded CMS' threshold for compliance actions (*see* 86 FR 6000 and 87 FR 27704). Each of these factors, on its own, represents significant non-compliance with an MA or Part D contract; therefore, the presence of any of these factors in an applicant's record during the past performance review period could allow CMS to deny its MA or Part D application.

CMS is now proposing to apply a past performance methodology to entities that seek to offer a new PACE program or expand an existing program. Our proposal would modify the regulations at Part 460 to permit CMS to consider an entity's past performance in determining whether to approve or deny a new application or an application to expand a current program. The proposed methodology for this evaluation would be similar to the methodology CMS uses when deciding whether to deny MA and Part D applications based on past performance. As with our MA and Part D past performance reviews, the purpose of our proposed PACE past performance reviews is to prevent organizations from expanding their PACE operations where the organization's past conduct indicates that allowing the organization to expand would pose a high risk to the success and stability of PACE and PACE participants. Like MA organizations and Part D sponsors, PACE organizations that have been under sanction, failed to meet fiscal soundness requirements, or been issued compliance actions above a certain threshold have demonstrated that they have had significant failures in operating their program. Consistent with the past performance standards for MA and Part D, and as we discuss in detail later in this proposed rule, we are proposing that CMS would deny an initial or service area expansion (SAE) application based on the same factors (other than low Star Ratings) that serve as the basis for denying an MA or Part D application. CMS does not propose to include Star Ratings in the past performance review for PACE because CMS does not calculate these measures for PACE organizations.

CMS accepts applications on designated quarterly submission dates from entities seeking to either establish a PACE program or expand an existing program. Similar to MA applications, and in accordance with § 460.18, CMS evaluates a PACE application based on information contained in the application itself, as well as information obtained by CMS (or the applicable State Administering Agency (SAA), which serves as the designated State agency for PACE), through on-site visits or any other means. If an organization meets all application requirements, CMS approves the application.

CMS is proposing to incorporate past performance reviews into the PACE application process to safeguard the program and ensure PACE participants are protected from the expansion of poorly performing organizations. The PACE program has seen significant growth in recent years, with increased numbers of both initial and expansion applications and steady increases in overall enrollment. This growth can be attributed in part to a legislative change that took effect in 2015 that allowed for-profit entities to operate PACE programs (see sections 1894(h) and 1934(h) of the Act). Prior to that change, only not-for-profit entities were eligible to offer PACE programs. At the end of calendar year 2016, a total of 121 approved PACE organizations were in operation, serving 37,584 predominantly dually-eligible participants. In calendar year 2021, CMS received 22 initial applications and 22 expansion applications. As of September 2022, there were 149 PACE organizations serving 54,643 participants in 32 states.

PACE participants are some of our most vulnerable beneficiaries. In order to enroll in a PACE program, the SAA must determine that the beneficiary needs the level of care required under the State Medicaid plan for coverage of nursing facility services (§ 460.150(b)(2)). Beneficiaries who need this level of care are generally frail, may have multiple conditions, and require extensive assistance with activities of daily living. The 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 (§ 460.98(a)). Each PACE organization must have a center, which PACE participants can visit weekly or even daily, based on each participant's needs and preferences. The PACE center must provide primary care services, nursing services, social services, restorative therapies (including physical therapy and occupational therapy), personal care and supportive services, nutritional counseling, recreational therapy, and meals (§ 460.98(c)).

Given the recent and anticipated future growth in PACE and the vulnerable populations that PACE organizations serve, CMS believes that the past performance of a PACE organization should be reviewed as part of the application process. Past performance evaluations would enhance

CMS' ability to ensure that initial PACE applications and applications for service area expansions from low performing organizations are denied. The ability to deny initial PACE applications or service area expansion applications submitted by organizations that we determine are poor performers helps to ensure that the organizations with which we have an agreement will be able to provide health care services to beneficiaries in a high-quality manner.

The PACE application review process is unique, and we have developed these proposals with that process in mind. Per the regulations at § 460.20(a) and (c), upon receipt of a complete PACE application, CMS must: (1) approve the application; (2) deny the application; or (3) issue a request for additional information (RAI) in the event there are deficiencies. CMS' deadline for these actions is within 90 days of submission of an initial application or for a service area expansion (SAE) application that includes both a proposed geographic expansion and a new center site, or within 45 days of submission of an SAE application that includes either a proposed geographic expansion *or* a new center site. If CMS issues an RAI, the applicant must respond to the RAI only when ready and able to submit a complete response that addresses all deficiencies cited in the RAI, which includes a complete State readiness review (SRR) report, as applicable. If CMS issues an RAI, the first review clock ends and the second and final review clock does not begin until the applicant submits a complete RAI response, which starts the second and final 45- or 90-day review clock, as applicable. As part of the application process, the applicable SAA must conduct an SRR at the applicant's proposed PACE center site (if applicable) to ensure that the PACE center meets the State's regulatory requirements. Applicants are required to submit documentation of the completed SRR report to CMS for applications that include a new PACE center site (*see* § 460.12(b)(2)). Per application instructions, the SRR report is the only required document that may be uploaded after the initial application submission, in response to CMS' RAI. In our experience, a response to a RAI may take anywhere from a few weeks to more than a year to receive, often because of the renovation or construction of a center site, attainment of building permits, and/or the need for a readiness review to be completed. The MA and Part D past performance review currently has a 12-month look back period which is defined as the most recent 12 months preceding the application deadline (*see* § 422.502(b) and 423.503(b)). Since MA and Part D applications are generally due in February of each year, this review period results in a 12-month look back period that covers the previous March through February of the year the applications are due. Similar to MA and Part D, we propose to use a 12-month review period under this PACE proposal, resulting in a review of an organization's past performance for the 12 months preceding the deadline established by CMS for the submission of PACE applications but also propose to apply the 12-month look back review upon receipt of the applicant's response to CMS' RAI. A 12-month look back period provides recent information on the operations of a PACE organization, which we believe is the best indicator of the PACE organization's current and future performance.

We propose, at § 460.18(c)(1)(i), to evaluate the following components of an applicant organization's past performance starting with the March 2024 quarterly application submission cycle: whether the organization was subject to an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40, even if the reasons for the sanction have been corrected and the sanction has been lifted; whether the organization failed to maintain fiscal soundness; whether the organization has filed for or is under State bankruptcy proceedings; and whether the organization has exceeded CMS' proposed 13-point threshold for compliance actions with respect to the PACE program agreement. We are proposing that, if any of those circumstances applies to the applicant organization, CMS may deny its initial or expansion application.

Specifically we propose at § 460.18(c)(1)(i)(A) to include the imposition of enrollment or payment sanctions under § 460.42 for one of the violations listed in § 460.40 as a reason for which CMS may deny a PACE application, as noted in the paragraph above. Currently, § 460.42 authorizes CMS to impose a suspension of enrollment or payment if a PACE organization commits one or more of the violations listed in § 460.40. Violations in § 460.40 include the failure of the PACE organization to provide medically-necessary services, discrimination in enrollment or disenrollment of individuals eligible to enroll in a PACE program based on health status or need for health services, and involuntary disenrollment of a PACE participant in violation of § 460.164. These violations are serious and egregious actions by the PACE organization. Organizations that have been sanctioned (enrollment or payment) based on their failure to comply with CMS' regulations have either admitted they failed to comply with PACE requirements or have appealed and a third party has upheld CMS' determination that the PACE organization has failed to comply with requirements. Because of the egregiousness of the actions that led to the PACE organizations' sanctions, we do not believe these organizations should be permitted to enter into new agreements, add new PACE sites, or expand their service area until the PACE organization corrects the issues that resulted in the sanction and ensures that such issues are not likely to recur.

We propose at § 460.18(c)(1)(i)(B) to include, as a basis for application denial, the failure to maintain a fiscally sound operation after the end of the trial period. For purposes of fiscal soundness, the trial period ends when CMS has reviewed independently audited annual financial statements covering three full 12-month financial reporting periods. The regulation at § 460.80(a) requires a PACE organization to have a fiscally sound operation. Under § 460.80(a)(1), a PACE organization must have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities. To monitor compliance with § 460.80(a)(1), CMS requires PACE organizations to submit certified financial statements on a quarterly basis during the trial period, and annually thereafter, unless CMS or the SAA determines that the organization requires more frequent monitoring and oversight due to concerns about fiscal soundness, in which case the organization may be required to submit certified financial statements on a monthly or quarterly basis (or both) (§ 460.208). Fiscal soundness is a key factor in CMS' evaluation of past performance because CMS has a responsibility to ensure the organizations that provide health care services to our beneficiaries have sufficient funds to allow them to pay providers and otherwise maintain operations. The failure of an organization to have a positive net worth puts PACE participants in jeopardy of not receiving necessary health care. In addition, organizations that are not fiscally sound may not be able to continue operations, causing the organization to close doors, leaving all their PACE participants without PACE coverage. Based on this, CMS believes it

is in the best interest of the program to add failure to maintain a fiscally sound operation—specifically, failure to have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities—to the list of reasons CMS may deny a new application or an expansion application from a PACE organization.

We propose to establish at § 460.18(c)(1)(i)(C) that CMS may deny the application of an organization that has filed for or is currently in State bankruptcy proceedings. Similar to an organization that lacks fiscal soundness, an organization that has filed for or currently is in State bankruptcy proceedings is at great risk of not having sufficient funds to cover costs associated with running a PACE program. In circumstances where an organization has filed for bankruptcy or is currently in State bankruptcy proceedings, the outcome often results in the closure of an organization's operations, putting beneficiaries at great risk. Examples of participants being at risk may include the inability to find adequate and timely care, care coordination issues, loss of providers (especially primary care providers who are employed by the PACE organization), as well as loss of the social and emotional support the PACE organization provides. Thus, permitting an organization to expand while under bankruptcy proceedings is not in the best interest of the PACE program and CMS should be able to deny an application from any organization that has filed for or is in State bankruptcy proceedings.

Finally, we propose to establish at § 460.18(c)(1)(i)(D) that CMS may deny an initial application or an expansion application for a PACE organization that exceeds the proposed 13-point threshold with respect to CMS-issued compliance actions. Proposed § 460.19(a) would specify that CMS may take compliance actions as described at proposed § 460.19(c) (discussed in this section of this proposed rule) if CMS determines that a PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and an SAA. PACE organizations are required to adhere to requirements in sections 1894 and 1934 of the Act and in CMS regulations at 42 CFR part 460. Proposed § 460.19(a)(1) would provide that CMS may determine that a PACE organization is non-compliant with requirements if the PACE organization fails to meet set performance standards articulated in sections 1894 and 1934 of the Act, regulations at 42 CFR chapter IV, and guidance. In addition, proposed § 460.19(a)(2) would establish that if CMS has not previously articulated a measure for determining compliance, CMS may determine that a PACE organization is non-compliant if its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

Currently, CMS issues three types of compliance actions: Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs).[203] These actions are CMS' formal way of recording an organization's failure to comply with statutory and regulatory requirements as well as providing notice to the organization to correct its deficiencies or risk further compliance and/or enforcement actions. They also serve to document the problem and, in some instances, request details on how the organization intends to address the problem.

CMS proposes to specify at new § 460.19(c) the types of compliance actions we currently issue. First, CMS proposes to specify that NONCs may be issued for any failure to comply with the requirements of the PACE organization's current or prior PACE program agreement. CMS typically uses NONCs to document small or isolated problems. They are the lowest form of a compliance action issued by CMS. CMS typically issues NONCs for the least egregious failures, such as a first-time offense, a failure that affects only a small number/percentage of participants, or issues that have no participant impact. An example of a failure that would lead to an NONC would be a failure to upload or correctly upload marketing materials.

Second, CMS proposes to specify that WLs may be issued for serious and/or continued noncompliance with the requirements of the PACE organization's current or prior program agreement. CMS typically issues WLs as an intermediate level of compliance action, between a NONC and a CAP. They are issued either when an organization has already received a NONC, yet the problem persists, or for a first offense for larger or more concerning problems, such as failure to provide medically necessary services. Unlike NONCs, these letters contain warning language about the potential consequences to the organization should the non-compliant performance continue. Similar to CAPs, WLs are issued for more egregious instances of non-compliance or continued non-compliance. However, they are issued when the egregiousness or continued non-compliance may not warrant a CAP. For example, a WL might be issued when a PACE organization has failed to have the full interdisciplinary team (IDT) involved in the review of participant care plans, which may have or did result in participants not receiving necessary care. CMS might determine, based on a review of factors such as the types of care not received, that the PACE organization's non-compliance does not warrant a CAP, and issue a WL instead.

Third, CMS proposes to specify that the last type of compliance action, the CAP, is the most serious type of compliance action and may be issued for particularly egregious or continued noncompliance. CMS may determine that the PACE organization has repeated, not corrected, or has a new deficiency which substantially impacts beneficiaries. In these cases, CMS requires the PACE organization to implement a CAP.

The CAPs described in this proposed provision are not the same as corrective actions issued under § 460.194(a)(2). CAPs issued under § 460.194(a)(2) require PACE organizations to take action to correct deficiencies identified by CMS or the State administering agency through reviews and audits of the PACE organization (§ 460.194(a)(2)). CMS has a formal audit process, which identifies non-compliance. CMS issues CAPs under 460.194(a)(2) as a result of reviews or audits. These CAPs are routinely requested and PACE organizations submit them to CMS as a means of addressing deficiencies identified during reviews or audits. CMS expects to continue to request CAPs as necessary under 460.194(a)(2) in response to deficiencies identified through reviews or audits; nothing about this proposal would change that process.

Consistent with the past performance methodology applicable to MA, we propose to assign points to each type of compliance action taken by CMS against PACE organizations. We then propose to apply a compliance action threshold to determine if the PACE organization that submitted the application exceeds the threshold and should be denied. The following points would be assigned: CAP—6 points, WL—3 points, NONC—1 point. CMS will then total the points accrued by the applicant organization, and if the total meets or exceeds 13 points during the 12-month review

[203] The CAPs CMS proposes to issue for purposes of compliance and take into account during past performance evaluations to determine whether to deny PACE organizations' applications would be separate and distinct from CAPs issued under § 460.194(a)(2), which are corrective action plans that are requested and received in the course of audits.

period, CMS may deny the organization's new or expansion application on the basis of past performance.

With the proposed addition of compliance actions as a basis for the denial of applications, CMS is also proposing to specify at new § 460.19(b)the factors we currently use to determine whether to issue a compliance action and the level of compliance action that should be issued.

At § 460.19(b)(1) through (6), we propose to put in regulations the factors we currently use when determining whether to issue a compliance action and what level of compliance action to issue. As discussed in the paragraphs that follow, CMS considers the following factors: the nature of the conduct, the degree of culpability of the PACE organization, the actual or potential adverse effect on participants which resulted or could have resulted from the conduct of the PACE organization, the history of prior offenses by the PACE organization or PACE organization's contractors or subcontractors, whether the non-compliance was self-reported, and other factors which relate to the impact of the underlying non-compliance or to the PACE organization's inadequate oversight of the operations that contributed to the non-compliance.

Proposed § 460.19(b)(1) would establish that CMS considers the nature of the PACE organization's non-compliant conduct. The nature of the conduct is relevant to CMS' determination of whether to issue a compliance action and the level of compliance action to take because failure to comply can range from an administrative issue to failure to provide necessary health care. Compliance issues that are less egregious in nature generally result in lower-level compliance actions.

Proposed § 460.19(b)(2) would provide that CMS considers the degree of culpability of the PACE organization. This factor is relevant because the PACE organization's failure may have been avoided if the PACE organization had performed differently. For example, if the PACE organization failed to properly train or failed to hire properly trained staff to assist participants in activities of daily living, such as bathing, and a participant fell and injured themself in the shower, the PACE organization would be more culpable than if staff were properly trained and the participant still injured themself. The PACE organization has a responsibility to do everything possible to ensure the safety of the participants, and its failure, either intentional or unintentional (for example, lack of training, lack of oversight, lack of staff) would be a factor in CMS' decision about the type of compliance action to take.

Proposed § 460.19(b)(3) would provide that CMS considers the effects or potential effect of a PACE organization's conduct on PACE participants. This factor is relevant because a PACE organization's failure to comply may have very different effects (or potential effects) on PACE participants and may affect varying numbers of participants. For example, an organization's failure to timely arrange for primary care could affect the vast majority of participants enrolled with that organization. However, an organization's failure to timely arrange for a very specific type of specialty care may affect only a few participants.

Proposed § 460.19(b)(4) would specify that CMS considers the history of prior offenses of a PACE organization or its related entities. A PACE organization's (or its related entity's) failure to comply is relevant because the PACE organization should have ongoing processes in place to correct deficiencies as they occur and ensure that deficiencies are not likely to recur. As mentioned later in this section, organizations that have had recurrent compliance issues may be subject to a higher level of compliance action. For example, a PACE organization that failed to provide transportation to participants one year ago may have received a NONC at that time. If the organization fails to correct this deficiency after first being cited with a NONC for the deficiency, CMS may escalate the continued failure to comply by issuing a WL, based on the PACE organization's past history and continued failure to correct the deficiency.

Proposed § 460.19(b)(5) would provide that CMS considers whether an organization self-reported a compliance failure. A PACE organization that self-reports that the organization has found the deficiency, such as through an internal audit, generally indicates that the organization is actively engaged in identifying and correcting compliance issues, and likely has initiated the corrective action to address the deficiency prior to CMS being made aware of the matter. CMS considers issues that are identified through specific requests made by CMS, the review of data CMS either has or has requested, or complaints that have come into CMS through sources such as 1–800–Medicare that or complaints that CMS has asked the PACE organization to provide as issues that are not self-reported. If an organization has self-reported a compliance issue, CMS may decide to lower the level of noncompliance (for example, issuing a NONC instead of a WL) because of the organization's transparency with respect to the non-compliant behavior, since it is possible CMS would not have found the deficiency if not for the self-reporting. However, even if the organization did self-report the issue, CMS may decide against lowering the level of compliance action if, depending on the factors identified above, to warrant a higher-level compliance action.

Finally, proposed § 460.19(b)(6) would provide that CMS considers the PACE organization's failure to adequately oversee its operations. For instance, if an organization fails to properly pay claims, is aware of the issue, and fails to correct it (for example, by processing the claims accurately), or if the organization fails to do any monitoring or auditing of its own systems to ensure proper claims payment is occurring, CMS could take that into account in determining whether to issue a compliance action and, if so, the level of compliance action.

As previously mentioned, CMS proposes in a new § 460.18(c)(1)(i)(D) that CMS would have authority to deny a new application or an expansion application if a PACE organization accumulates 13 or more compliance action points during the applicable proposed 12-month look back period. This would be the equivalent of just over two CAPs. Any organization whose performance results in issuance of two CAPs and a NONC, or whose performance results in any combination of compliance actions that add up to 13 points, should not be permitted to expand.

CMS is proposing at § 460.18(c)(1)(ii) that CMS could also deny an application from an organization that does not hold a PACE program agreement at the time of the submission, if the applicant's parent organization or another subsidiary of the same parent organization meets the past performance criteria for denial proposed in § 460.18(c)(1)(i). Specifically, if an initial applicant is a legal entity under a parent organization that has a PACE program agreement, or if there are other organizations under the same parent that have a PACE program agreement, and the parent's PACE application or the other related organizations' PACE applications would be denied based on any of the factors proposed in § 460.18(c)(1)(i), we would also deny the new entity's application based on the

past performance of other members of its corporate family. It is likely that similar structures, policies, and procedures are used across legal entities that are part of the same parent organization, increasing the likelihood that any part of a parent organization that has at least one poorly performing legal entity may be at increased risk of poor performance. In addition, using other legal entities' performance when the new applicant has no history would also prevent organizations from manipulating CMS'past performance methodology by establishing new legal entities and using those to submit PACE applications in order to avoid having CMS take into account the troubled performance history of the parent organization or its subsidiaries when reviewing the new legal entity's PACE application.

It would be especially important, when CMS reviews a new application from a legal entity that does not have activity that would constitute the past performance of that legal entity as a PACE organization, for CMS to be able to consider information from the current or prior PACE program agreements of the parent organization of the applicant, and from members of the same parent organization as the applicant. We are more frequently seeing initial PACE applications that represent unique and distinct legal entities that are part of a broader parent organization. In one recent instance, we reviewed an initial PACE application for a new legal entity under a parent organization that already had created a number of separate and unique legal sub-entities. In this case, in accordance with § 460.18(a) and (b), CMS considered the known adverse audit findings of other legal entities that were under the same parent organization, and which resulted in formal enrollment sanctions for the other legal entities. In the review of the new legal entity's application, we determined that the new legal entity was under the same ''umbrella'' as the legal entities that had been sanctioned, because many of the key members of the executive leadership team were served in similar roles for both the sanctioned entities and the new applicant. CMS denied the application due to the nature of the deficiencies that led to formal sanctions for the related organizations.

We are also proposing one exception to this policy. A PACE organization that acquires an organization that would have an application denied based on any of the factors in § 460.18(c)(i) would have a 24 month ''grace'' period that would extend only to the acquiring parent organization. This means that the acquiring organization would still be able to enter into new agreements or expand its programs under other agreements for which there are no performance issues for 24 months following the acquisition. It is in the best interest of the PACE program to allow PACE organizations that are meeting CMS' requirements to acquire poor performing PACE organizations without being penalized based solely on their acquisition. As stated in proposed § 460.18(c)(ii), this ''grace'' period would be limited to 24 months from the date of acquisition. We believe this 24-month grace period would give an acquiring PACE organization sufficient time to ''turn around'' a poor performing organization.

Finally, we propose to add a new paragraph § 460.18(d) to provide CMS the explicit authority to consider prior termination history as part of the evaluation of an initial PACE or expansion application. Specifically, we propose that if CMS has terminated a PACE organization's program agreement under § 460.50(a), or did not renew the program agreement, and that termination or non-renewal took effect within the 38 months prior to the submission of an application by the PACE organization, CMS would be able to deny the PACE organization's application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant satisfies all other application requirements. The 38-month period is consistent with the Part D regulations at 42 CFR part 423. Because PACE organizations that offer Part D are subject to 42 CFR parts 423 and 460, we believe a 38 month period is appropriate. This ensures PACE applicants are not unduly burdened by having two different sets of past performance requirements, resulting in two different timeframes. CMS does not unilaterally terminate PACE organizations' program agreements without significant failures, which are often failures affecting the furnishing or quality of care provided to PACE participants. Furthermore, a PACE organization whose program agreement has been terminated may appeal. If the PACE organization chooses to appeal and the termination is subsequently upheld through the appeals process, the organization has been found to have committed an action or actions that are egregious enough to warrant a termination. If the organization does not appeal, then the organization is acknowledging CMS' ability to terminate its PACE program agreement. Allowing organizations to come back into the PACE program when they have failed to adequately implement a prior agreement would be contrary to CMS' purpose of ensuring that high quality care is provided to PACE participants. However, we believe that an organization, after a 38-month period, may have improved its operations sufficiently for us to consider its submission of an initial application.

D. Clarification of PACE Enforcement Authority for Civil Money Penalties and Intermediate Sanctions (§ 460.40(b))

In the final rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)'' (84 FR 25610), which appeared in the June 3, 2019 issue of the **Federal Register**, CMS amended § 460.40 by adding paragraph (b), which establishes that CMS has the discretion to take alternative enforcement actions in the form of civil money penalties (CMP) or a suspension of enrollment of Medicare beneficiaries by, or payment to, a PACE organization if CMS makes a determination that could lead to a termination of a PACE program agreement under § 460.50. In order to terminate a contract under paragraph (b) of § 460.50, CMS or the State administering agency must determine that both of the following circumstances exist: (1) there are significant deficiencies in the quality of care furnished to participants; or the PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including making payment to an individual or entity that is included on the preclusion list, defined in § 422.2; and (2) within 30 days of the date of the receipt of written notice of a determination made under paragraph § 460.50(b)(1), the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies, or failed to continue implementation of the plan of correction.

In circumstances where CMS has made a determination under § 460.50 that could lead to termination, CMS would likely impose a CMP or suspension of enrollment and/or payment on a PACE organization prior to terminating the PACE organization, as authorized by § 460.40(b) (unless there was imminent risk to a PACE participant). This is because CMS views CMPs and suspensions of enrollment and/or payment as corrective in nature, since they are imposed when the PACE organization has been found noncompliant, and they provide time for the PACE organization to correct the issue(s) that led to the noncompliance

with the ultimate goal of mitigating any actual or potential harm for PACE participants.

As previously stated, in order for CMS to take any enforcement action (CMP, suspension of enrollment or payment, termination) on a PACE organization based on the grounds for termination set forth in § 460.50(b), the PACE organization must fail to develop and successfully initiate a plan to correct the deficiencies, or fail to continue implementation of the plan of correction within 30 days of receiving notice. Given that CMPs and suspensions of enrollment and/or payment are corrective in nature and imposed prior to termination, CMS believes that providing PACE organizations an opportunity to correct prior to imposing a CMP or suspensions of enrollment and/or payment is unnecessary and most importantly an impediment to CMS' ability to protect PACE participants from potential harm.

For these reasons, CMS proposes to revise § 460.40(b) by adding the following: ''If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administrating agency has to determine that the circumstances in 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension.''

E. Personnel Medical Clearance (§ § 460.64 and 460.71)

Sections 1894(f)(4) and 1934(f)(4) of the Act grant CMS broad authority to issue regulations to ensure the health and safety of individuals enrolled in PACE. The PACE regulations at §§ 460.64 and 460.71 protect participants' health and safety by requiring PACE staff to be medically cleared of communicable diseases before engaging in direct participant contact.

In the 1999 PACE interim final rule (64 FR 66242), CMS added § 460.64, which sets forth certain personnel qualification requirements for PACE staff. When drafting these regulations, CMS reviewed the personnel requirements of other Medicare and Medicaid providers that serve populations similar to PACE participants (for example, home health agencies, nursing facilities, intermediate care facilities) (*Id.*). CMS also explained that in drafting these provisions we took a flexible approach that relied on State requirements as much as possible (*Id.*).

In the 2002 interim final rule, titled ''Medicare and Medicaid Programs; Programs of All-inclusive Care for the Elderly (PACE); Program Revisions'', which appeared in the **Federal Register** October 1, 2002 (67 FR 61496), CMS added § 460.71, which sets forth oversight requirements for PACE employees and contractors with direct patient care responsibilities. CMS noted the importance of adding this new section due to the vulnerable frail population served by the PACE program and the increased opportunity for a PACE organization to contract out participant care services due to the amendment in the 2002 interim final rule which allowed PACE organizations to provide PACE Center services through contractual arrangements (67 FR 61499). One of the new requirements that the 2002 interim final rule adopted was the requirement at § 460.71(b)(4) for PACE organizations to develop a program to ensure that all staff furnishing direct participant care services be ''free of communicable diseases.'' In the rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions'', which appeared in the **Federal Register** on December 8, 2006 (71 FR 71243), herein after referred to as the 2006 PACE final rule, CMS amended § 460.64 to align with § 460.71(b)(4) by adding the requirement at § 460.64(a)(5) that employees and contractors with direct participant contact ''[b]e medically cleared for communicable diseases and have all vaccinations up-to-date before engaging in direct participant contact.'' When adding this requirement at § 460.64(a)(5), CMS noted, ''It is standard practice in the health care industry that an individual must be cleared as free of communicable disease prior to employment'' and ''this is even more important with a frail elderly population considering their complex medical conditions and increased susceptibility'' (71 FR 71267). CMS also indicated in the 2006 PACE final rule that we were amending § 460.71 ''to be consistent with the general personnel qualifications'' (71 FR 71328); as amended, § 460.71(b)(4) specified that all direct participant care staff and contractors must be ''free of communicable diseases and have all immunizations up to date before performing direct participant care.'' In the June 2019 final rule, CMS amended the language in § 460.71(b)(4), which referred to staff being ''free of communicable disease'' so that it instead referred to staff being ''medically cleared for communicable disease'', which is the phrasing used in § 460.64(a)(5) (84 FR 25636). CMS explained that this inconsistency in language had caused confusion among PACE organizations about whether to attach the same meaning to ''medically cleared for communicable diseases'' and ''free of communicable diseases.'' CMS amended § 460.71(b)(4) to use the phrase ''medically cleared for communicable disease'' that appears in § 460.64(a)(5) so that the two provisions would be consistent and contain the same language (84 FR 25636).

Based on our audit and oversight experience, we have found that PACE organizations have many varied interpretations of what it means for staff to be ''medically cleared for communicable disease.'' As a result, PACE organizations do not implement consistent methods for assessing or detecting communicable diseases. For example, some organizations require individuals to have a physical examination by a physician, physician assistant, or nurse practitioner, whereas others allow for an assessment to be conducted by staff who are not licensed to evaluate individuals' medical conditions, and still other organizations only require a self-assessment completed by the individual seeking employment. While a physical examination by a physician, physician assistant, or nurse practitioner is sufficient for clearing an individual of a communicable disease, CMS does not believe that assessments conducted by unlicensed staff or self-assessments are sufficient to meet the requirement.

For the last 2 years, the COVID–19 pandemic has demonstrated a need for a more comprehensive approach to infectious disease management and prevention. The elderly population was hit particularly hard by the pandemic, which highlighted the insufficiency of existing safeguards in nursing homes and similar care environments. While PACE participants live independently unless care is needed in a specific setting, they still require nursing home-equivalent levels of care. That care is typically provided in participants' homes and in the PACE centers, and participants interact with many different types of staff in those settings. We believe that the inconsistent approach to medical clearance that has been noted on audit has led to insufficient medical clearance, which places PACE participants at risk of exposure to communicable diseases including, but not limited to, COVID–19. Therefore, we are proposing to amend §§ 460.64 and 460.71 to require all PACE organizations to develop and implement a comprehensive medical clearance process with minimum conditions that CMS deems acceptable to meet the requirement of medical clearance and to better protect the frail

and vulnerable population served by PACE.

We are proposing several modifications to the requirement at § 460.64(a)(5). Currently, the language states that staff must ''be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.'' First, we propose to separate the requirement to be medically cleared for communicable diseases from the requirement to have all immunizations up to date. We believe these are two separate and distinct requirements, and each serves a unique and important purpose. Specifically, we propose to create a new paragraph (a)(6) that would specify that each member of the PACE organization's staff (employee or contractor) who has direct contact with participants must have all immunizations up to date before engaging in direct participant contact. Proposed paragraph (a)(6) would include language specifying that, at a minimum, vaccinations identified in § 460.74 must be up to date. In response to the COVID–19 pandemic, we amended § 460.74 by adding paragraph (d), which requires PACE organizations to develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19 (see 86 FR 61555 at 61618). We believe citing back to this immunization requirement in new § 460.64(a)(6) would help ensure that PACE organizations are considering COVID–19 vaccination status when ensuring staff have received all immunizations. Currently, while the regulation requires that ''all immunizations are up to date'', CMS has not defined what those immunizations must include, other than the COVID vaccination referenced in § 460.74. Rather, PACE organizations have historically set their own requirements for what vaccinations should be considered as ''required'' for their staff with direct participant contact. We considered defining all immunizations as including those recommended by the Advisory Committee on Immunizations Practices (ACIP) for health care workers, including when they are applicable based on individual criteria such as age or past infection.[204] However, based on the PACE population we are considering limiting the required vaccinations for PACE staff with direct participant contact to the Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B.[205] We solicit comment on whether any specific vaccinations other than the COVID–19 vaccination should be required for each member of a PACE organization's staff (employee or contractor) that has direct participant contact. We are particularly interested in commenters' views on the vaccinations recommended by ACIP and whether they should be included among the immunizations required for PACE staff with direct participant contact. We would also solicit comment on whether we should use the ACIP list without modifications, or whether we should only require this subset of vaccines; Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B.

At § 460.64(a)(5), we propose to require that each member of a PACE organization's staff (employee or contractor) who has direct participant contact be medically cleared of communicable diseases both before engaging in direct participant contact and on an annual basis. Requiring staff to be medically cleared of communicable diseases annually will ensure that medical clearance is not a one-time requirement, but rather an ongoing responsibility. In our review of State requirements, we noted numerous states have some requirement for an ongoing or annual screening, and therefore it is reasonable to also propose that for PACE organizations. We are soliciting comment on adding this annual requirement into the medical clearance provision.

We also propose adding requirements to define what would constitute an acceptable medical clearance process. When considering what to require for medical clearance we considered many different provider types, including hospital systems, and what different states require for medical clearance. We also considered the PACE population, and its vulnerability to communicable diseases. Based on these factors, we believe the best practice for PACE organizations is to have each individual with direct participant contact on a PACE organization's staff (employee or contractor) undergo a physical examination by a provider acting within the scope of their authority to practice. A physical examination requirement would ensure that staff are appropriately medically cleared prior to engaging in direct participant contact. We therefore propose at § 460.64(a)(5)(i) to require that staff who engage in direct participant contact must be medically cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of the practitioner's authority to practice. This exam could be done at the PACE center by the primary care provider already employed by the PACE organization, and therefore, it would not be difficult to operationalize. We also propose at § 460.64(a)(5)(ii) that as part of the initial physical examination, staff with direct participant contact must be determined to be free of active Tuberculosis (TB) disease. It is important for organizations to screen for TB because it is a deadly disease and baseline testing is recommended by the CDC for all health care professionals.[206] Testing for TB is widely available and relatively simple and we believe that a TB test should be conducted as part of any initial physical examination that is screening for communicable disease. We are proposing to add ''initial'' into this regulation text, because annual TB testing is not recommended by the CDC unless a risk assessment is performed which indicates it is necessary.[207]

However, we also understand that not all individuals who have direct participant contact have the same level of risk of having communicable diseases (through previous exposures), and requiring a physical examination may be overly burdensome. Therefore, we propose that, as an alternative to medically clearing all staff with direct participant contact for communicable diseases based on a physical examination, the PACE organization could opt to conduct an individual risk assessment as allowed under proposed § 460.64(a)(5)(iii). If the results of the risk assessment indicate the individual does not require a physical examination in order to be medically cleared, then a physical examination would not be required. This proposal would allow organizations to medically clear staff with direct participant contact by either conducting a physical examination, or by conducting a risk assessment of the individual and determining based on the results that no physical exam is needed.

Proposed § 460.64(a)(5)(iii) would identify the minimum requirements that the PACE organization must satisfy if it chooses to conduct a risk assessment for medical clearance. First, we propose to

[204] Vaccines Indicated for Adults Based on Medical Indications | CDC.

[205] Meningococcal vaccination is also a recommended immunization by ACIP; however, this immunization is recommended for microbiologists who are routinely exposed to Neisseria meningitidis, which we do not believe is relevant to the PACE population or PACE staff.

[206] *https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm.*

[207] *https://www.cdc.gov/tb/topic/testing/healthcareworkers.htm.*

specify at § 460.64(a)(5)(iii)(A) that the PACE organization must develop and implement policies and procedures for conducting a risk assessment on each individual with direct participant contact based on accepted professional standards of care, for example, standards of care for screening influenza. For example, a risk assessment may include questions about an individual's current symptoms (if any), past diagnoses (specifically in regard to communicable diseases), and/or recent travel to determine whether the individual is at risk of being infected with a communicable disease. While each organization should have the operational latitude to develop its own policies and procedures, consistent with these proposed requirements, to assess if an individual needs a physical examination, when drafting and implementing these policies and procedures, organizations should consider any applicable professional standards of care and/or any applicable State guidelines on medical clearance.

Proposed § 460.64(a)(5)(iii)(B) would specify that the purpose of the risk assessment is to determine if, based on the assessment, a physical examination is necessary for an individual. As previously mentioned, we believe that the best practice for medical clearance is a physical examination by a physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice. However, by allowing PACE organizations to conduct a risk assessment to determine if some individuals on a PACE organization's staff who engage in direct participant contact (employee or contractor) may not need a full physical exam would provide some administrative flexibility for organizations.

Proposed § 460.64(a)(5)(iii)(C) would require that the results of the risk assessment be reviewed by a registered nurse, physician, nurse practitioner or physician assistant. We initially considered limiting these professions to primary care providers. However, we believe that because this risk assessment is used to screen staff to determine whether a physical exam is needed but is not itself a physical exam meant to diagnose an individual, it would be appropriate for a registered nurse to review those results and help triage staff that may need a more thorough exam. However, because registered nurses are not permitted to diagnose individuals, it would be inappropriate for a registered nurse to perform the physical examination.

Finally, we propose to identify at § 460.64(a)(5)(iii)(D) the minimum requirements we would expect to be included in a PACE organization's risk assessment. First, we propose to require that any risk assessment developed by a PACE organization would assess whether staff have been exposed to or have symptoms of the following diseases: COVID–19, Diphtheria,[208] Influenza,[209] Measles,[210] Meningitis,[211] Meningococcal Disease,[212] Mumps,[213] Pertussis,[214] Pneumococcal Disease,[215] Rubella,[216] Streptococcal Infection,[217] and Varicella Zoster Virus.[218] When considering what communicable diseases to include in the risk assessment, we considered several resources, including State resources for reportable diseases, and we also considered information from the CDC on communicable diseases. We are proposing to include the aforementioned diseases in the risk assessment because they are commonly reportable and transmissible via air or through droplets. In addition to the aforementioned specific diseases, we are also proposing to include any other infectious disease noted as a potential threat to public health by the CDC in order to allow for situations such as the recent COVID–19 pandemic where a new communicable disease creates a situation that poses a threat to public health, and is significant enough that the CDC notes the threat. We would expect in those situations for a PACE organization to update its risk assessment to include that new public threat in the screening process. While we would want to account for new threats to public health, we recognize that the proposed language is more open to interpretation than listing specific diseases that may arise in the future. When developing this proposal, we considered CDC's Health Alert Network, the agency's primary method of sharing cleared information about urgent public health incidents with public information officers; Federal, State, territorial, Tribal, and local public health practitioners; clinicians; and public health laboratories.[219] It is likely that any threat to public health related to communicable diseases would be shared through this mechanism, but we solicit comment on whether this would be an appropriate source to consider, or whether there are other sources that CMS and PACE organizations should use. Because we recognize these sources may change over time, we are not inclined to add a specific source into regulation, but we solicit comment on that as well.

We also propose to require that a PACE organization's initial risk assessment must determine whether staff are free of active TB disease. We considered adding TB into the list of diseases in § 460.64(a)(5)(iii)(D)(1), however, we believe screening for this disease through a series of questions about exposure or symptomatology would not be sufficient to rule out this condition when conducting an initial evaluation of an individual. As aforementioned, the availability of testing for TB is wide spread, and all staff should be determined to be free of active TB prior to having direct participant contact. In order to ensure staff are free from active TB, a PACE organization should conduct either a skin test (with a chest x-ray when indicated) and/or blood test, as well as a physical examination if indicated, during the initial risk assessment process.

While we have proposed an alternative to requiring a physical examination for every employee or contractor with direct participant contact (that is, by allowing PACE organizations to conduct a risk assessment), we are soliciting comment on whether we should eliminate the risk assessment from this proposal, and require all staff who engage in direct participant contact (employee or contractor) to undergo a physical examination by a physician in order to be medically cleared. As indicated earlier in our discussion, we believe a physician, nurse practitioner, or physician assistant is best qualified to determine if an individual is medically cleared from communicable diseases.

We discuss and account for the burden of updating the policies and procedures in the collection of information requirements section of this proposed rule.

As we previously discussed, the requirement for medical clearance with respect to communicable diseases resides both in §§ 460.64(a)(5) and 460.71(b)(4). In section § 460.71(b)(4), we propose to amend the current language to state that all employees and contracted staff furnishing care directly to participants must be medically

[208] *https://www.cdc.gov/diphtheria/.*

[209] *https://www.cdc.gov/flu/.*

[210] *https://www.cdc.gov/measles/.*

[211] *https://www.cdc.gov/meningitis/.*

[212] *https://www.cdc.gov/meningococcal/index.html.*

[213] *https://www.cdc.gov/mumps/.*

[214] *https://www.cdc.gov/pertussis/.*

[215] *https://www.cdc.gov/pneumococcal/.*

[216] *https://www.cdc.gov/rubella/.*

[217] *https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/selected-infections/group-a-strep.html.*

[218] *https://www.cdc.gov/chickenpox/hcp/.*

[219] *https://emergency.cdc.gov/han/index.asp.*

cleared for communicable diseases before engaging in direct participant contact and on an annual basis as required under § 460.64(a)(5). We also propose to add language to a newly designated § 460.71(b)(5) to require all employees and contracted staff to have all immunizations up-to-date before engaging in direct participant contact, including, at a minimum, the vaccine requirements identified in § 460.74. Under our proposal, current paragraphs (b)(5) and (b)(6) would be redesignated as paragraphs (b)(6) and (b)(7). We believe that by modifying this provision as proposed we would not be increasing the burden on PACE organizations as they are already required to ensure employees and contractors have all immunizations up-to-date.

F. PACE Contracted Services (§ 460.70)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require 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. 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.

The 1999 PACE interim final rule (64 FR 66234) was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment, participant rights, and quality assurance. As we noted in that rule, that rulemaking implemented the directive in sections 1894(f)(2) and 1934(f)(2) of the Act to incorporate into regulation the requirements applied to PACE demonstration programs under the Protocol,[220] to the extent consistent with provisions of sections 1894 and 1934 of the Act. Among the required services included in the original PACE Protocol and the 1999 PACE interim final rule were medical specialty services. Specifically, the PACE Protocol identified a minimum subset of services that a PACE organization must provide, which was used to create the regulation at § 460.92. These medical specialty services included, but were not limited to, anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, general surgery, thoracic and vascular surgery, and urology.

In the 2006 PACE final rule (71 FR 71244), CMS reviewed and addressed comments concerning the list of required services in § 460.92. Some commenters had expressed the view that the list was too extensive and noted that it was longer than the list of required services for nursing facilities, which the commenters suggested presented a potential dilemma for states to establish the cost effectiveness of PACE compared to the cost for nursing facilities. Other commenters recommended that CMS reevaluate the list to ensure it included the minimum requirements necessary to protect the health, safety, welfare, and rights of consumers in the PACE program (71 FR 71280).

In response to these comments, CMS reiterated that the scope of benefits identified in sections 1894(b) and 1934(b) of the Act, and the requirement that PACE cover, at a minimum, all Medicare covered services, all Medicaid covered services, and any other services determined necessary by the IDT (71 FR 71280). However, following review of the comments, CMS determined it was not possible to provide a complete list of all inpatient, outpatient, physician specialty, care planning, and social support services that must be furnished to participants if ordered by the IDT (71 FR 71281). For this reason, CMS removed the listing of required services in § 460.92, including medical specialties; not because those services are not required in PACE, but because the PACE benefit covers even more services than the ones that had been initially listed under § 460.92, and we believed including an incomplete listing of specialties might be misunderstood to mean that specialties we did not list were not required services. Instead, CMS revised § 460.92 to state that PACE organizations are required to cover all Medicare covered services, all Medicaid covered services included in the State plan, and any other services determined necessary by the IDT.

While the list of specialties was removed from § 460.92, CMS did not remove § 460.112(c) which establishes that PACE participants have a right to a choice of providers, within the PACE organization's network, that is sufficient to ensure access to appropriate, high-quality health care. Specifically, CMS stated that each participant has the right to choose both their primary care provider and specialists within the PACE network (71 FR 71296). CMS stressed that ''consumers with complex or serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers'' (*Id.*). CMS noted in that discussion that we expect the PACE organization to have contractual arrangements with primary care physicians (PCPs) and specialists to meet the needs of their participants, and that CMS and the SAA would determine compliance with the requirement as part of the application process and through ongoing monitoring. (*Id.*).

Since making these changes, we have seen through our monitoring and oversight efforts that some PACE organizations are not providing timely access to medical specialists. For example, based on data collected during 2021 audits (the most recent complete year of audit data), approximately 70% of organizations that were cited for a failure to provide necessary services were cited, at least in part, based on not providing necessary access to medical specialists. These delays in access have, in some instances, contributed to adverse impacts to participants including injuries, hospitalizations and death. Based on our experience, we have found that delays in accessing medical specialists sometimes occur as a result of PACE organizations not having contracts in effect for the medical specialties commonly utilized by PACE participants, such as the types of medical specialties enumerated in the 1999 PACE interim final rule. Therefore, we are proposing to add back into the regulation the list of medical specialty services identified in the original PACE protocol that the PACE organizations must ensure access to as a minimum requirement. Specifically, we propose to amend by adding language to § 460.70(a)(1) that specifies that PACE organizations are required to execute and maintain a contract with the following medical specialties: anesthesiology, audiology, cardiology, dentistry, dermatology,

[220] The Protocol references the PACE protocol published by On Lok, Inc. A copy of the original PACE protocol is included as an attachment to the 1999 PACE interim final rule (see 64 FR 66298). This Protocol was later replaced by the PACE program agreement.

gastroenterology, gynecology, internal medicine, nephrology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, general surgery, thoracic and vascular surgery, and urology. We considered adding the medical specialties to § 460.92, where it was originally located; however, the requirement is better suited in § 460.70(a)(1) for several reasons. First, most, if not all, medical specialists do not work directly for the PACE organization, and rather are contracted providers that would need to adhere to the other requirements in § 460.70. Second, by adding this requirement into the contracted services provision of the regulation, we believe it will allow CMS and State agencies to better assess PACE organizations' readiness to enroll by ensuring these contracts are in place prior to participants enrolling in the organization.

While we are proposing to add a list of medical specialty services back into the PACE regulations, we continue to maintain that this is not an exhaustive list of all medical specialists that the PACE organization may be required to provide access to. For example, if the IDT determines that a participant needs to see a hematologist, the PACE organization would be required to provide access to that specialist in a timely manner. The specialties we are proposing to add in § 460.70(a)(1) would represent a minimum requirement for all PACE organizations; each PACE organizations should consider the needs of its participants to determine what additional medical specialists may be necessary for its network to be sufficient. While we are proposing to add back into regulation the 25 medical specialty services identified in the original PACE protocol, we solicit comment on whether CMS should include the following additional specialty services in the list of minimum required services: endocrinology, hematology, immunology, neurology, colorectal surgery, palliative medicine, infectious disease, physical medicine and rehabilitation. Additionally, while we consider psychiatry to be an important behavioral health specialist since they write prescriptions for psychiatric medicines, we are soliciting comment on whether there should be other behavior health specialists required in this list, such as psychologists or licensed clinical social workers. When submitting comments on this proposal, we ask that commenters indicate whether they have any concerns with CMS adding any or all of the, previously discussed, specialty services to the list. For commenters who do have such concerns, we ask that you describe your concerns with specificity, so that we can more fully understand the nature and basis of your concerns. We believe a PACE organization must be able to access all these specialty services when a participant needs them, and based on our oversight experience, that these additional specialty services are often necessary for the PACE population.

We also propose at new § 460.70(a)(2) to require a PACE organization to execute these contracts with specialists prior to enrollment of participants, and to require the PACE organization to maintain such contracts on an ongoing basis to ensure participants receive appropriate and timely access to all necessary care and services. We clarify that we are not requiring PACE organizations to contract with individual specialists in situations where the PACE organization has contracted with a provider or practice that offers multiple specialties. In an instance of a medical provider or practice offering multiple specialties, the contract between the practice or provider, such as a hospital group, and the PACE organization would meet the requirement to contract with whatever specialties were included in the practice or provider group. We believe it is appropriate for organizations to be able to demonstrate that they have sufficient and direct access to these commonly needed specialists prior to participants enrolling in the organization. Through our auditing and oversight efforts, we have seen lengthy delays in specialist referrals when an organization has to contract with a new specialist, and waiting until a participant enrolls or has need of the specialist may create unreasonable delays in the participant being able to access that specialist. Additionally, as we noted in the 2006 PACE final rule (71 FR 71296), PACE organizations are financially responsible for all of their participants' health care needs, and delays in referrals for specialist services may have a significant impact on the PACE organization's financial viability. Failure to provide timely specialist referrals may lead to more expensive care, including the need for institutionalization, which can drive up operating costs for a PACE organization.

At proposed § 460.70(a)(3), we would establish that a PACE organization must make reasonable and timely attempts to contract with medical specialists. PACE organizations are responsible for ensuring that participants have reasonable and timely access to medical specialty services, and that PACE organizations are responsible for taking appropriate steps in ensuring that they have suitable contracts in place in order to facilitate timely access to medical specialty services. We are not proposing to establish specific criteria for determining whether ''reasonable'' attempts have been made for purposes of proposed § 460.70(a)(3), as what is reasonable would depend on the facts and circumstances of the case. For example, in an area with multiple providers in a specific medical specialty, it would not be reasonable to only attempt to contract with a single provider, if that provider indicated they were unwilling to contract with the PACE organization.

We further propose to establish at § 460.70(a)(3)(i) that if at any time a PACE organization is unable to directly contract with a specific entity to provide specialist services to participants, the PACE organization must still ensure ongoing access to necessary care and services that would otherwise be provided to participants by a contracted specialist, and that the participant's needs are met, through a different mechanism which may include hospitalization. As noted in the 2006 PACE final rule (71 FR 71296), we understand that in certain circumstances executing multiple contracts for a specific specialty may be difficult due, in part, to a limited number of specialists in certain geographic areas; however, we stress that PACE organizations continue to be responsible for meeting all of the participant's needs, even if there is not a direct contract in place. Additionally, under our proposal at § 460.70(a)(3)(ii) we would expect an organization to promptly report any contracting problems to CMS and the State Administering Agency (SAA), and include information on what attempts were made, the reason why the contract was not effectuated, and the PACE organization's plan to provide access to the necessary services. This reporting may be initiated by the PACE organization when reasonable attempts to contract have been made, and were unsuccessful; or it may be done in response to CMS or the SAA inquiring as to the status of the contracts. For example, during the State readiness review, the SAA may inquire as to the status of the PACE organization's contracts with medical specialists. When reporting these contracting issues to CMS or the SAA, the PACE organization should be prepared to

describe its attempts to contract with medical specialists, why a contract was not able to be effectuated, and how the PACE organization plans to ensure participants' needs are met. For example, if there is only one specialist in a service area, and they are not accepting new participants, the PACE organization must show its attempts to contract and how it will ensure participants are able to receive the care that the specialist would have provided. In other words, in this example, the PACE organization must show that they reached out to the one specialist in the area, attempted to contract with that specialist, and were unsuccessful in those attempts.

Finally, in order to account for PACE organizations that may choose to employ some medical specialists directly, such as dentists and podiatrists, proposed § 460.70(a)(4) would exempt a PACE organization from the contract requirements in § 460.70(a)(1) and (2) with respect to a particular medical specialty if a PACE organization employs one or more individuals prior to contracting who are legally authorized and, if applicable, board certified, in the particular medical specialty. While we expect that most of the specialists in this list would be contracted by the organization, we understand that there are times when a PACE organization may directly employ one of these specialty providers. In those instances, assuming the participants have sufficient access to that type of specialist through that employment, the PACE organization would not be required to contract with additional providers in that specialty. However, the organization must have the specialist actively employed prior to enrollment of participants in order for the exception to be met and cannot rely on future employment to satisfy this requirement. We believe that by modifying this provision as proposed we would not be increasing the burden on PACE organizations as they are already required to either obtain and maintain contracts with or employ medical specialists.

G. Timeframes for Coordinating Necessary Care (§ 460.98(b)(4) and (c))

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act specify 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. 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. 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, at § 460.98(a), we require a PACE organization to be responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year. In order to meet participants' needs, PACE organizations must provide necessary services as expeditiously as the participant's condition requires; however, there is no specific timeframe on the delivery of services in PACE. The creation of a specific timeframe for delivery of services has been contemplated since the 1999 PACE interim final rule, where we noted that it was critical that care not be delayed and that the participant receive comprehensive care that maintains his or her functional status (64 FR 66251). However, we also noted that we recognize that some changes in the participant's plan of care (for example, installing a wheelchair ramp at the participant's home) may require more time to accomplish, and therefore CMS did not specify a timeframe for delivering services (*Id.*). Although we chose not to specify a timeframe for delivering services in the 1999 PACE interim final rule, we solicited comment on the necessity of requiring a specific timeframe (64 FR 66251). In the 2006 PACE final rule, we noted that commenters were split on the topic of timeframes and indicated that further consideration of this issue was needed before CMS would propose to adopt a specific timeframe (71 FR 71292). We discussed this issue again in 2020 when publishing a proposed rule (85 FR 9138) and when finalizing the January 2021 final rule (86 FR 6034). We stated at that time that we did not believe we could implement a specific timeframe given the vast array of service that PACE organizations provide (*Id.*). We also noted that determining how quickly a service must 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 (*Id.*). Therefore, we finalized § 460.98(b)(4), which requires 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.

Despite the difficulty in creating a specific timeframe for the delivery of services, we continue to identify through monitoring and oversight situations where PACE organizations are jeopardizing participant health and safety by not promptly providing necessary services and that the cause for these delays is sometimes related to organizations failing to promptly schedule or arrange a service following approval from the IDT. Based on data collected through audits, in the past 4 years, over 80% of audited PACE organizations have been cited for a failure to provide services in a way that is necessary to meet participant needs. To address these concerns, we propose to establish timeframes for arranging the provision of IDT approved services for PACE participants. Requiring PACE organizations to promptly act to arrange or schedule necessary services creates accountability for expeditious service delivery while offering flexibility for wide ranges of services and variation in urgency. These timeframes would allow the IDT to determine how quickly a service is needed based on the participant's condition, but would ensure that the services were quickly arranged and scheduled to ensure that they are not forgotten or neglected in the course of other business. In drafting this proposal, we considered both the MA regulations in Part 422 and Medicaid regulations in Part 438; however, because PACE is not only an insurer, but also a direct care provider, we do not believe that the timeframes in these programs are appropriate for use in PACE. We therefore also considered the long-term care regulations in Part 483. Under those regulations, skilled nursing facilities and nursing facilities are required to refer residents to a dentist within 3 calendar days when a resident has lost or damaged their dentures (see

§§ 483.55(a)(5) and 483.25(b)(3)). This requirement to refer residents to a dentist has a similar intent of ensuring the facility is promptly arranging for the necessary services for a resident.

Presently, § 460.98 specifies PACE program service delivery requirements related to access to services, provision of services, minimum services furnished at each PACE center, PACE center operation, and center attendance. We propose to amend § 460.98 by, first, redesignating current paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), respectively. Next, we propose to add a new paragraph (c) with the heading ''Timeframes for Arranging and Providing Services.'' In addition, we propose to move the requirement in current paragraph § 460.98(b)(4) to provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs to new paragraph (c)(4). We also propose to redesignate paragraph (b)(5) as (b)(4).

We propose that the new section § 460.98(c) would have four subparagraphs related to the timeframes for arranging and providing services. A ''service'' as defined in § 460.6 means all services that could be required under § 460.92, including items and drugs. Given the vast array and differing availability of services in PACE, we considered creating one uniform timeframe for arranging all services, but ultimately determined that was not appropriate. Regarding the MA and Part D programs, we note that there are significant differences in the timeframes for approving and providing services under each program. In Part D, the timeframes for approving and providing coverage of medications are much shorter than the timeframes for approving and providing services in MA. Therefore, we believe it is appropriate in PACE to also create a distinct timeframe for medications.

We propose at new § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after the primary care provider orders the medication. We consider the use of the words ''arrange and schedule'' to mean that the PACE organization has notified the participant's pharmacy or pharmacy service of the approved medication order and has provided all necessary information for the pharmacy to fill the medication order and provide the participant with timely access to the medication. This timeframe would not require the medication to be delivered to the participant within that 24 hours, unless the participant's condition required delivery in that timeframe. Additionally, we believe that ''no later than 24 hours after the primary care provider orders the medication'' is a fair timeframe and critical to meet the immediate care needs of participants, as lack of prompt access to many medications could result in deterioration of a participant's condition. Additionally, as pharmacies are usually open seven days a week, and prescriptions can often be submitted electronically, we believe that there is limited burden on the organization in meeting this timeframe. We solicit comment on this proposal, including whether CMS should consider other maximum timeframes for PACE organizations to arrange and schedule the dispensing of medications, or exceptions to this requirement. An example of the type of comment we hope to receive would be one that addressed whether over-the-counter medications should be included in this timeframe, as those medications may have different methods of being filled. We solicit comment on alternative maximum medication authorization timeframes less than or greater than 24 hours after the primary care provider orders the medication and request that such comments address how the alternative timeframes would ensure participant health and safety.

We propose to establish at new § 460.98(c)(2) the requirement that PACE organizations arrange or schedule the delivery of IDT approved services, other than medications, as identified in proposed § 460.98(c)(2)(i), as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the IDT or a member of the IDT first approves the service, except as identified in proposed § 460.98(c)(3). As previously noted, this requirement would apply to all services that are not medications. When developing this timeframe, we considered our experience with monitoring and auditing organizations, and feedback we have received from organizations in previous rules. In the 2006 PACE final rule (71 FR 71292), we noted that in comments that were submitted in response to a comment solicitation we had included in the 1999 PACE interim final rule, in which we sought input on whether to impose a timeframe under which PACE organizations would be required to initiate services after a revision to a participant's plan of care, some commenters indicated that they believe a maximum timeframe of 5 calendar days should apply to initiating service delivery following an approved change in the plan of care. We considered, but decided not to propose a 5 calendar day timeframe, because a 5 calendar day timeframe may be operationally impractical for instances in which a PACE organization receives a request late in the business week that requires scheduling a service with a specialist or medical office closed on weekends and Federal holidays. We also considered whether other programs had timeframes we could draw from, but because PACE is both an insurer and provider and is required to provide such a broad range of services, we did not find a comparable program or provider directly applicable to PACE for purposes of scheduling services. We then considered the needs of the participant and the operational challenges of the organization when developing the timeframe. Based on all of these factors, we are proposing a 7-day timeframe, which we believe will balance the needs of the participant with the administrative responsibilities of a PACE organization. Based on our oversight efforts, we understand that some organizations already act to arrange services within a timeframe of 7 calendar days or sooner, as the participant's health condition requires. We are also proposing to describe the action that the PACE organization must take within the proposed 7-day timeframe in terms of when services are arranged or scheduled with the expectation that the delivery of the service would not need to occur within this timeframe; instead, the PACE organization would be expected to take affirmative steps to make sure the approved service was set up, scheduled, or arranged within this timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved. For example, if the IDT approved increasing a participant's physical therapy frequency from two to three times per week, we would expect the PACE organization to conduct outreach to the participant's physical therapist or the physical therapist's administrative support to set up a third weekly appointment within 7 calendar days of the IDT approval. If the IDT determines that the participant should see an ophthalmologist, the PACE organization would be required to schedule the appointment within 7 days of approval. We would not expect the delivery of the service (in this example, the actual appointment) to occur within 7 days, only that the appointment has been scheduled within that timeframe. Following the ophthalmologist

appointment, if the IDT determined that eyeglasses were necessary upon review of the provider's recommendation, the PACE organization would then be required to arrange for the provision of the eyeglasses within the timeframes proposed at § 460.98(c)(2), which may include a purchase order for eyeglasses. The 7-day timeframe begins once approval is made by the IDT or a member of the IDT. We would again stress that this is a maximum timeframe, and if a participant's condition required the service more quickly, the PACE organization would be expected to act to arrange the service more quickly. Our proposal would require that the timeframe of 7 calendar days begin after the date the IDT or a member of the IDT approves the service. We invite comment on alternative maximum timeframes for arranging or scheduling IDT-approved services. In particular, we are interested in knowing if PACE organizations continue to believe that 5 days is an appropriate timeframe to schedule and arrange services, and if not, whether commenters recommend a different maximum timeframe that is between 6 to 10 (that is, 6, 7, 8, 9 or 10) calendar days after the date the IDT or a member of the IDT approves the service. Additionally, we solicit comment on whether there are additional definitions of ''arrange or schedule'' that CMS should consider. We request that such comments address how the alternative timeframes would ensure participant health and safety, especially if commenters advocate for a timeframe longer than 7 calendar days.

We propose at § 460.98(c)(2)(i)(A) through (D) to define which services are included in the definition of interdisciplinary team approved services. We propose to specify at § 460.98(c)(2)(i)(A) that this includes services approved by the full IDT. These services would typically be the ones discussed and approved during the course of IDT meetings. This would be any service other than a medication. For example, if the IDT met and decided to approve physical therapy for six weeks, the date it made that approval would then trigger the timeframe of 7 calendar days. We propose to specify at § 460.98(c)(2)(i)(B) that IDT approved services also include services approved by a member of the IDT. We believe this is important to emphasize to ensure that service determination requests that are immediately approved by a member of the IDT under § 460.121(e)(2) are subject to this new timeframe. Additionally, we have seen instances where a member of the IDT, in the course of their duties, may approve a service as necessary for a participant. For example, a physical therapist may approve extra therapy sessions during the course of their treatment. Or, following a recommendation from a cardiologist, the PCP may approve a Holter monitor for the participant. In these instances, when a service is approved by a member of the IDT, we would expect the PACE organization to promptly arrange and schedule the approved service within the 7 calendar days. We propose at § 460.98(c)(2)(i)(C) that IDT approved services include services ordered by a member of the IDT. We routinely see PCPs ordering necessary services as a part of managing the participant's condition, including but not limited to specialist consults, labs, and medications. We would consider an IDT member ordering a service as approving that service for purposes of proposed § 460.98(c)(2). For example, if a recommendation for a CT scan is made by an oncologist, and the PCP approves and orders the CT scan, we would expect the CT scan to be arranged within 7 calendar days from when the PCP approved/ordered the scan. We believe that it is important to specifically distinguish the types of approvals that could occur, as a part of the IDT's routine course of business, any one of which would trigger the timeframe of 7 calendar days to schedule or arrange for the delivery of services. We would also emphasize that under our proposal at § 460.98(c)(2), the timeframe begins when the IDT or a member of the IDT first approves a service. Therefore, when any one of these approvals occurs, on that first instance, the timeframe would be initiated. For example, if the IDT determined that labs were required for a participant in order to test their kidney function, the timeframe to arrange those labs would begin on that date, even if the PCP did not write an order for the labs until a later date or time. We solicit comment on this provision, including additional considerations that could improve the definition of IDT approved services.

We propose at the new § 460.98(c)(3) to exclude routine or preventative services from the timeframe to requirement in § 460.98(c)(2) when certain requirements are met. We understand that PACE organizations may not be able to schedule every service within 7 calendar days, especially when the service is a routine service and not needed until much later in time. In order to satisfy this exception, we propose at § 460.98(c)(3)(i) through (iii) three requirements that would all need to be met in order for a PACE organization to be exempt from the timeframe included in § 460.98(c)(2). First, we propose at § 460.98(c)(3)(i) that the PACE organization must document that they were unable to schedule the appointment for the routine or preventative service due to circumstances beyond the control of the PACE organization. We believe that this is a reasonable exception, as we understand that for some routine appointments, for example, an annual eye exam, the specialist or contracted provider may limit how far out they are willing to schedule appointments. We would expect the PACE organization to document its efforts to arrange or schedule the appointment and that they were unable to schedule the appointment due to the specialist's availability. Second, we propose to establish at § 460.98(c)(3)(ii) that the PACE organization is exempt from the timeframe as long the participant does not have a change in status that requires the service to be provided more quickly. We recognize that a participant's condition may change, and a routine appointment may become more urgent as the participant's condition deteriorates. The exception to the timeframes in § 460.98(c)(2) only applies when a participant does not experience a change that would require the service to be provided more quickly. If the participant does experience a change in status that would warrant a faster appointment, the exception would no longer apply, and the PACE organization would be expected to schedule the service as necessary. Last, we propose at § 460.98(c)(3)(iii) that the PACE organization may be excepted from the timeframes to arrange a service if the PACE organization provides the service as expeditiously as the participant's condition requires. While we understand that there may be circumstances that prevent a PACE organization from scheduling some routine or preventative services, ultimately the PACE organization always remains responsible for ensuring the participant's needs are met. We believe it is in the best interest of participants and administratively reasonable to require all three of these factors in order to exempt PACE organizations from the maximum timeframes proposed at § 460.98(c)(2) and to limit the exemption to services that are routine or preventative. We solicit comment on this provision, including suggestions of additional exceptions to the timeframes at § 460.98(c)(1) and (2).

We propose to redesignate § 460.98(b)(4) as § 460.98(c)(4) without further modification. Thus, the new § 460.98(c)(4) would maintain the requirement that PACE organizations provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical physical emotional, and social needs. The proposed timeframes in § 460.98(c)(1) through (c)(3) are maximum timeframes for arranging the provision of services. PACE organizations must continue to provide or deliver services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs, which may require the PACE organization to arrange or schedule services sooner than the timeframes proposed in § 460.98(c). Under redesignated § 460.98(c)(4), PACE organizations would continue to make determinations on how quickly to provide a service on a case-by-case basis, and we would expect PACE organizations to demonstrate that services were provided as expeditiously as the participant's medical, physical, emotional, and social needs require during monitoring efforts by CMS.

We estimate a one-time burden for PACE organizations to update their policies and procedures to reflect the proposed timeframes for arranging and providing services. We discuss and account for the one-time burden for their policies and procedures to reflect the proposed timeframes for arranging and providing services in the Collection of Information Requirements section and through an update to the CMS–R–244 PRA package.

We solicit comments on this proposal.

H. Care Coordination (§ 460.102)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require PACE organizations to provide 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. 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. 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. Additionally, sections 1894(b)(1)(C) and 1934(b)(1)(C) of the Act specify that PACE organizations must provide services to participants through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services in accordance to regulations, and specify the covered items and services that will not be provided directly by the entity, and to arrange for delivery of those items and services through contracts meeting the requirements of regulations.

CMS has codified requirements pertaining to the interdisciplinary team (IDT) at § 460.102. Although the PACE organization is ultimately responsible for providing comprehensive, multidisciplinary care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, the IDT has a critical role in enabling the PACE organization to meet these responsibilities. As established in the 1999 PACE interim final rule (64 FR 66248), the IDT, then referred to as the multidisciplinary team, must comprehensively assess and meet the individual needs of each participant. In addition, the IDT is responsible for the initial assessment, periodic reassessments, the plan of care, and coordinating 24-hour care delivery (64 FR 66249). Through monitoring and oversight activities, CMS has determined that further specification of IDT responsibilities is necessary to ensure appropriate compliance with the program requirements. While many IDTs appropriately apply the multidisciplinary approach to providing care, our monitoring efforts have shown that some organizations do not ensure the IDT is fully involved in coordination of care for participants across all care settings. We have also seen organizations interpret IDT responsibilities to coordinate care narrowly. For example, an IDT may order care, but then fail to ensure that the care has been provided in accordance with those orders and that the participant's needs were met.

Current § 460.102(d)(1)(i) specifies that the IDT has responsibility for the initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery. Section 460.102(d)(1)(ii) states that the IDT is responsible for 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). We propose several amendments to § 460.102(d)(1). First, we propose to redesignate current paragraph (d)(1)(ii) as paragraph (d)(1)(iii), and to add a new paragraph (d)(1)(ii). We also propose to add a new paragraph (d)(1)(iv).

We propose to modify § 460.102(d)(1) to specify that the IDT is responsible for all activities as described at § 460.102(d)(1)(i) through § 460.102(d)(1)(iv) for each participant. The proposed regulation would include the words ''for each participant'' to emphasize that these responsibilities are not general requirements the IDT must fulfill, but rather specific responsibilities the IDT must fulfill for each participant. The 1999 PACE interim final rule (64 FR 66288) established basic requirements for the IDT at § 460.102(a), including that the IDT must comprehensively assess and meet the individual needs of each participant and that each participant be assigned an IDT at the PACE center that they attend. Since inception of PACE, CMS has considered the IDT responsibilities to apply to all participants at the individual level. CMS believes the current language in § 460.102(d)(1) does not preclude the proposed requirements at § 460.102(d)(1)(i) through § 460.102(d)(1)(iv) from applying at the individual participant level. However, the addition of ''each participant'' more clearly emphasizes CMS' expectations.

We propose to modify the requirement at § 460.102(d)(1)(i) to include only the IDT's responsibility for the initial assessment, periodic assessment, and plan of care and to relocate the requirement pertaining to the IDT's responsibility to coordinate 24-hour care delivery to new § 460.102(d)(ii). We believe the responsibility to coordinate 24-hour care delivery is a separate and distinct requirement from the requirements to conduct assessments and create or revise a plan of care. Additionally, we propose to add a paragraph heading at § 460.102(d)(1)(i) to read ''Assessments and Plan of Care'' in order to reflect the proposed modified content of the paragraph.

We propose to move IDT coordination of care requirements from § 460.102(d)(1)(i) to new § 460.102(d)(1)(ii), because separating IDT coordination of care responsibilities at § 460.102(d)(1)(ii) from the

assessment and care planning responsibilities at § 460.102(d)(1)(i) improves the provision's readability. We also propose to modify the language of § 460.102(d)(1)(ii) and to add 5 paragraphs at § 460.102(d)(1)(ii)(A) through (E) to further specify what coordination of 24-hour care delivery involves by defining what actions we consider care coordination to include.

We propose at new § 460.102(d)(1)(ii) to require that the IDT coordinate and implement 24-hour care delivery that meets participant needs across all care settings. We added language into this requirement about meeting the participant's needs across all care settings in order to clarify the scope of the IDT's care coordination for all participants, including, but not limited to, participants residing in long-term care facilities. We also added ''implementation'' into the requirement at § 460.102(d)(1)(ii) because we have seen through audits and monitoring efforts that PACE organizations are interpreting ''coordination'' narrowly, and they do not consider it to include all necessary components of care coordination, such as ensuring the implementation of care. As a result, we have seen problems with medication orders being implemented appropriately, wound care not being done in accordance with orders, and other necessary services not being provided to the participant. This proposal will further emphasize CMS' expectations of IDT coordination of care responsibilities and lead to better care for participants, especially participants residing in acute and long-term care facilities.

This proposal is consistent with the current statutory and regulatory requirements for PACE organizations and the IDT. 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 (see § 460.98(a)). PACE organizations are also responsible for furnishing comprehensive medical, health, and social services that integrate acute and long-term care. We have received requests to explain the difference between the PACE organization's responsibility to furnish care, and the IDT's responsibility to coordinate care. As we explained in the January 2021 final rule (86 FR 6036), PACE organizations are responsible for furnishing comprehensive services to PACE participants. The IDT, which consists of a subset of PACE organization's employees or contractors, is responsible for certain activities, such as coordinating care, which includes services that are furnished by the IDT as well as services furnished by other employees and contractors of the PACE organization. The proposed requirement at § 460.102(d)(1)(ii) for the IDT coordinate and implement 24-hour care delivery that meets participant needs across all care settings aligns with this interpretation, as the IDT is not always responsible for directly furnishing or providing the care to participants, but it always maintains responsibility for coordinating care for participants.

As previously noted, we are proposing to add 5 subparagraphs at § 460.102(d)(1)(ii)(A) through (E) that further specify IDT coordination responsibilities across all care settings. We propose at § 460.102(d)(1)(ii)(A) that the IDT is responsible for ordering, approving, or authorizing all necessary care in order to clarify CMS expectations regarding one aspect of the IDT care coordination responsibilities. PACE is a program designed around the IDT being responsible for authorizing and ordering all care that is needed for PACE participants. In fact, contractors, including medical specialty providers, must agree to furnish only those services authorized by the PACE IDT at § 460.70(d)(5)(i). We believe the proposed responsibilities at § 460.102(d)(1)(ii)(A) are important aspects of coordinating care that are inherent to the IDT's established and central role in care coordination.

We propose at § 460.102(d)(1)(ii)(B) to establish that the IDT is responsible for communicating all necessary care and relevant instructions for care. As discussed in connection with proposed § 460.102(d)(1)(ii)(A), the IDT is already responsible for authorizing all care the participant receives; however, in order for the participant to actually receive the care, the IDT must communicate the orders and relevant instructions to the appropriate individuals. For example, while a PCP may order a specialist consult, it is often scheduling or administrative staff that are responsible for actually arranging the appointment. As a part of coordinating care, the IDT must ensure that it communicates the necessary care and instructions to those individuals that need to know, for example, the individuals who will schedule, arrange, or provide the care and services. We contemplated adding further specificity in regulation about who those individuals may be, but we believe that it would encompass too many individuals for us to identify. For example, for a participant residing in a nursing facility, the IDT would need to ensure it communicated orders and instructions for care to the facility staff. For scheduling appointments, the IDT may need to communicate orders to administrative staff. We believe the IDT would be in the best position to identify the staff that need to know the information, and therefore we are leaving this proposed regulatory provision broad.

We propose to specify at § 460.102(d)(1)(ii)(C) that the IDT is responsible for ensuring care is implemented as it was ordered, approved, or authorized by the IDT. We have seen through oversight and monitoring efforts that while the IDT will order or authorize care, the team does not always follow through on ensuring that the care is provided in accordance with those orders. For example, a PCP may order wound care 3 times a week, but then the IDT will not follow through on ensuring that the wound care is actually done in accordance with those orders. As previously discussed, the 1999 PACE interim final rule (64 FR 66279) established the IDT as instrumental in controlling the delivery, quality, and continuity of care. Part of controlling the delivery and quality of care is ensuring that the care that is ordered, approved or authorized is actually provided.

We propose at § 460.102(d)(1)(ii)(D) to establish that the IDT is responsible for monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs. The IDT cannot appropriately coordinate 24-hour care delivery without also ensuring that it remains alert to the participant's condition by monitoring and evaluating the participant's condition. While the IDT is responsible for making sure that care is implemented in accordance with the approved or authorized orders, the IDT also remains responsible for ensuring the participant's needs are met through that care. For example, if the PCP orders wound care 2 times a week but the wound continues to worsen, the PCP should consider whether a new order is necessary in order to meet the participant's needs.

We propose to specify at § 460.102(d)(1)(ii)(E) that the IDT is responsible for promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant. The IDT's responsibilities for a participant do not end when care is authorized or ordered. As we stated in the 2006 PACE final rule (71 FR 71289), it is important for the IDT to monitor and respond to any changes in a participant's condition. It is important that the IDT respond promptly and modify care when it is determined that the participant's needs

are not currently being met. For example, if the PCP writes an order for blood pressure medication but then notes during a later assessment that the medication is not working, we would expect the PCP and the IDT to consider alternative medications or treatments that might better meet the participant's needs.

We propose to redesignate current § 460.102(d)(1)(ii) as § 460.102(d)(1)(iii) and add the title ''Documenting Recommended Services'' for improved readability. No further modifications are proposed for this provision.

We propose to add § 460.102(d)(1)(iv) to require the IDT to review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, and employees and contractors, including medical specialists. As discussed earlier, the IDT is responsible for authorizing, approving and ordering all care, including care recommended from contracted providers. This means that a participant may not receive necessary care until the IDT considers and approves or authorizes those recommendations that were made by the provider or specialist. Through monitoring and oversight activities, we have identified instances where the IDT is not promptly reviewing recommendations from urgent and emergency care providers, as well as employees and contractors. Based on data collected during the 2021 audits, approximately 75 percent of audited PACE organizations were cited based on a failure to review and act on recommendations from specialists in a manner necessary to meet the needs of the participant. Delayed review of recommendations and action on recommendations can delay the provision of necessary care and services, and can jeopardize participant health and safety. To address these concerns, we propose timeframes for the IDT to review and take action on recommendations from urgent and emergency care providers, as well as employees and contractors. As we stated in the January 2021 final rule (86 FR 6132), we do not believe we could implement a specific timeframe for the provision of services, given the vast array of services that PACE organizations provide and variation in individual participant needs. However, we believe requiring the IDT to promptly act on recommendations from urgent and emergency care providers, as well as employees and contractors, creates accountability for expeditious service delivery while offering flexibility for wide ranges of services and variation in urgency.

The timeframes we propose at § 460.102(d)(1)(iv)(A) through (C) would be maximum timeframes within which the IDT must review, assess and determine whether service recommendations from urgent and emergency care providers, as well as employees and contractors, are necessary to meet the participant's medical, physical, social, or emotional needs, and if so, promptly arrange and furnish the service in accordance with the timeframes at § 460.98(c). Under § 460.98(b)(4) (which we propose to redesignate as § 460.98(c)(4)), PACE organizations must continue to provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs. In order to meet the participant's needs, the IDT may need to review and act on recommendations sooner than the timeframes proposed in § 460.102(d)(1)(iv). Nothing in § 460.102(d)(1)(iv) would require the IDT to approve all recommendations; however, we would expect that the IDT review, assess, and act on the recommendation. That action would either be to either make a determination to approve or provide the recommended service or make a determination to not approve or provide the recommended service. If the IDT makes a determination to approve or provide a service, it must arrange and schedule the service in accordance with § 460.98(c). If the IDT makes a determination not to approve or provide a service, we would expect the IDT to document the reason(s) for not approving or providing the recommended care or services in accordance with current § 460.102(d)(1)(ii), which, as previously noted, we propose to redesignate as § 460.102(d)(1)(iii) and § 460.210(b).

We propose at § 460.102(d)(1)(iv)(A) to establish that the appropriate member(s) of the IDT must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs within 24 hours from the time of the participant's discharge. We considered multiple factors when proposing a 24-hour timeframe. We believe the 24-hour timeframe is necessary and reasonable due to the following considerations. First, this timeframe would be limited to only those recommendations made by hospitals, emergency departments and urgent care providers, and it would not apply to recommendations made by other providers or more routine appointments. Second, we considered that PACE is responsible for the needs of the participant 24 hours a day, every day of the year. When a participant is discharged from one of these settings there may be recommendations made or care needed, that cannot wait until the next business day. For example, a participant who is discharged from the hospital on a Saturday with a recommendation for antibiotics should not have to wait until Monday to have their prescription ordered or approved by the IDT. Third, we are proposing to not require that the full IDT be involved in assessing and acting on these recommendations, but rather the appropriate member(s) of the team as determined by the IDT. We do not anticipate that the full IDT would need to be involved in all decisions relating to recommendations made by hospitals or urgent care centers. It would likely be 1 or 2 IDT members that would ultimately be responsible for these recommendations and therefore a shorter timeframe is reasonable. For example, for the post discharge recommendation for antibiotics previously described, the IDT PCP may be the only discipline required to review and act on the medication request, since the PCP is responsible for ordering care and medications. We invite comment on alternative maximum timeframes for IDT review of all recommendations from hospitals, emergency departments, and urgent care providers and to make a determination on the recommendation's necessity; we are particularly interested in commenter's perspectives on timeframes of 12 hours, 48 hours, and 72 hours from the time of the participant's discharge. We request that such comments address how the commenter's preferred/recommended timeframe would ensure participant health and safety.

We propose to require at § 460.102(d)(1)(iv)(B) that the appropriate member(s) of the IDT must review all recommendations from other employees and contractors and make a determination with respect to whether the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 5 calendar days from the date the recommendation was made. We have seen through monitoring and audits where recommendations have not been considered or acted upon for significant periods of time, which has contributed to delays in the provision of necessary

care. While we do not believe that all recommendations made by all types of employees and contractors need to be responded to as quickly as recommendations from hospitals, urgent care providers, or emergency departments, we do believe the IDT must act promptly to consider the recommendations made, and, when the IDT deems the recommended care necessary, it must authorize the care. The proposed 5-day timeframe would represent the maximum amount of time a PACE organization would have to determine whether a recommended service is necessary, and we would expect the IDT to consider the participant's condition in determining whether it is necessary to make a determination sooner than 5 days after the recommendation is made. Additionally, we propose that the timeframe would begin when the recommendation is made, not when the recommendation is received by the IDT. We have seen through monitoring instances of PACE organizations not making initial requests for consult notes from a participant's appointment with a specialist until months after the appointment has taken place, and only learning at that time that a recommendation was made during the appointment. It is important that the PACE organization promptly act on recommendations, and it is our expectation that they develop processes with their employees and contractors to ensure the IDT is receiving recommendations in a manner that allows the IDT to determine the necessity of the recommended services within the proposed timeframe. We invite comment on alternative maximum timeframes for IDT review of all recommendations from other employees and contractors and to make a determination on the recommendation's necessity. We are particularly interested in commenters' perspectives on whether we should adopt a 3 calendar day timeframe, a 7 calendar day timeframe, or a 10 calendar day timeframe. We request that commenters address how the alternative timeframes would ensure participant health and safety.

We propose to establish at § 460.102(d)(1)(iv)(C) that, if recommendations are authorized or approved by the IDT or a member of the IDT, the services must be promptly arranged and furnished under § 460.98(c), as proposed. As discussed in section VI.G. of this proposed rule, we are proposing timeframes for the IDT to promptly arrange and schedule services that are authorized, ordered or approved by the IDT or a member of the IDT. If a recommendation is made by a contractor or an employee, and the IDT or a member of the IDT approves or orders that recommended service, we would expect the PACE organization to arrange and schedule the service in accordance with the proposed regulations at § 460.98(c). We are proposing distinct timeframes depending on the facts and circumstances of the situation and the service at issue. For example, if a hospital, at the time of discharge, makes a recommendation for a medication, the appropriate members of the IDT would have 24 hours to act on the recommendation, and if approved and ordered by the PCP, another 24 hours to arrange for the medication to be dispensed under proposed § 460.98(c)(1). In this scenario, because the recommendation is being made by a hospital, the timeframe to act on the recommendation is 24 hours under the proposal at § 460.102(d)(iv)(A), and because the recommended service is a medication, the timeframe to arrange the service is 24 hours from the date of the order under the proposal at § 460.98(c)(1). If a specialist recommends a medication, then the IDT would have 5 calendar days to make a determination with respect to the recommendation, and if it is approved and ordered, 24 hours to arrange for the medication to be dispensed. If a recommendation is made from a contractor such as a medical specialist for a service that is not a medication, the IDT would have 5 calendar days to consider and act on the recommendation, and then, if approved or authorized, the PACE organization would have 7 calendar days to arrange or schedule the approved or authorized service.

The timeframe to schedule the service would begin the day the IDT or a member of the IDT approves or authorizes the recommendation. We emphasize again that these timeframes are maximum timeframes that the IDT and PACE organization should consider when reviewing recommendations. For some recommendations, such as an MRI to be done in 3 months, these timeframes would be sufficient to ensure that the service is approved and arranged before the service is needed. However, there are other recommendations made where it would not be appropriate for the IDT to take a full 12 calendar days to assess and act on a recommendation, and then arrange and schedule it. For example, if a cardiologist indicated that the participant needed an urgent coronary artery bypass graft, we would expect that the IDT and PACE organization act upon that information in a more expeditious manner.

We are not scoring this provision in the Regulatory Impact Analysis section because the IDT is already required to comprehensively assess and meet the individual needs of each participant, including ensuring the participant's access to all necessary covered items and services 24 hours per day, every day of the year. We believe that by modifying this provision as proposed we would not be increasing burden on PACE organizations, as they already consider these items on a routine basis. We are also not scoring this provision in the Collection of Information section since all information impacts of this provision have already been accounted for under OMB control number 0938–0790 (CMS–R–244).

I. Plan of Care (§ 460.106)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require 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. 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.

In the 1999 PACE interim final rule (64 FR 66251), CMS developed requirements for participant plans of care based on the requirements in Part IV, section B of the original PACE Protocol. Those requirements were finalized in the 2006 PACE final rule (71 FR 71292) and they included: prompt development of a comprehensive plan of care by the IDT that specified the care needed to meet the participant's medical, physical, emotional, and social needs as identified in the initial comprehensive assessment; identification of measurable outcomes to be achieved; implementation, coordination, and monitoring of the

plan of care whether the services were furnished by PACE employees or contractors; reevaluation of the plan of care on at least a semiannual basis; development, review, and reevaluation of the plan of care in collaboration with the participant or caregiver, or both; and documentation of the plan of care, and any changes made to it, in the participant's medical record.

In 2010, in response to questions from PACE organizations, CMS issued a subregulatory document titled, ''Care Planning Guidance for PACE Organizations.'' This care planning document provided detailed guidance for developing, implementing, monitoring, reevaluating, and revising plans of care. The care planning document also provided guidance on interdisciplinary team involvement in the plan of care and what content or care should be included in the participant's plan of care. While this document stressed that care plans should be comprehensive and include the participants medical, physical, social and emotional needs; it also noted that not all care received by the participant would need to be included in the care plan, and instead, could be tracked and documented through discipline specific progress notes. The guidance stated that, ''Each PACE organization must define what care is integrated into the participant's plan of care, and what discipline-specific care is appropriately documented and monitored by the respective discipline specialist in the progress notes.'' [221]

Since that time, CMS has seen through oversight and monitoring efforts that participant care plans are often sparse and may not fully detail the care received by a participant. We have noted that organizations are relying heavily on providing and documenting care through discipline-specific progress notes, rather than through incorporation into a more comprehensive and formal plan of care.

In the June 2019 final rule (84 FR 25675), CMS added additional requirements around the development of a comprehensive plan of care. As part of the modifications made during the June 2019 final rule, we added at § 460.104(b) the requirement that within 30 days of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire IDT. The June 2019 final rule also added § 460.104(b)(1), which provides that if, in developing the plan of care, the IDT determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the plan of care. CMS explained in the June 2019 final rule that if the IDT does not believe a PACE participant needs a certain service as it relates to the IDT care plan assessment findings and, therefore, does not authorize that service, the IDT must document the rationale for not including the service in the plan of care (84 FR 25643). CMS also noted that we would expect the plan of care to reflect that the participant was assessed for all services, even where a determination is made that certain services were unnecessary at the time (*Id.*).

In addition to the modifications at § 460.104(b), in the June 2019 final rule, CMS also amended § 460.106 in order to provide additional clarity with respect to the development and content of the plan of care process (84 FR 25646). Among other changes, CMS added at § 460.106(b) three new requirements related to the interventions that must be included in a participant's plan of care. Specifically, CMS added requirements for PACE organizations to utilize the most appropriate interventions for each care need that advance the participant toward a measurable goal and outcome (§ 460.106(b)(3)); identify each intervention and how it will be implemented (§ 460.106(b)(4)); and identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes (§ 460.106(b)(5)).

Despite the addition of these requirements in the June 2019 final rule, we continue to find that PACE organizations are struggling with developing, implementing, monitoring, reevaluating, and revising plans of care. While the addition of § 460.104(b)(1) has helped organizations create more robust initial care plans for participants, we have seen through our oversight and monitoring process that these care plans become more sparse over time, and care initially included in the plan of care will be omitted in subsequent revisions and handled through discipline-specific progress notes as the participant's enrollment continues. We acknowledge that documenting detailed information about participant care and services in discipline-specific progress notes is necessary and an accepted standard practice; however, this should not be done in lieu of a comprehensive plan of care that addresses the participant's needs. The purpose of a plan of care is to allow the different IDT disciplines to discuss a participant's needs and develop interventions and goals, as a team. The IDT approach to care management and service delivery is a statutory requirement, and is one of the requirements that is essential to the PACE program and cannot be waived (*see* section 1894(f)(2)(B)(iii) of the Act). As we explained in the 2006 PACE final rule (71 FR 71285), we believe a well-functioning IDT is critical to the success of the PACE program as the team is instrumental in controlling the delivery, quality, and continuity of care. Members of the IDT should be knowledgeable about the overall needs of the participant, not just the needs that relate to their individual disciplines. In order to meet all of the health, psychosocial, and functional needs of the participant, team members must view the participant in a holistic manner and focus on a comprehensive care approach. By handling care through discipline-specific progress notes, the team role in discussing and monitoring that care is removed, and individual team members provide care in a more isolated and individualized approach. The plan of care is a tool that allows the IDT to assess a participant holistically, and develop interventions and goals that may cross disciplines. We also believe that failing to develop comprehensive plans of care poses a risk to participants enrolled in PACE organizations by making it harder for the organization to track and monitor the provision of services. When information is documented throughout a medical record in discipline-specific progress notes, instead of being consolidated in a single comprehensive plan of care, it prevents employees and contractors from quickly or easily locating necessary information and, as a result, may contribute to care not being provided as necessary or in a timely manner. Since the June 2019 final rule became effective, CMS has completed 40 PACE audits and we have identified a failure to provide services or delays in providing services in 37 of the 40 audits conducted. Although this non-compliance cannot be directly attributed to a failure to consolidate information into a comprehensive plan of care, our audit findings suggests that the coordination and delivery of necessary services is a challenge for PACE organizations.

Finally, in addition to seeing concerns related to the content of care plans, we have also seen on audit that participant and caregiver involvement in the care planning process tends to be minimal and primarily occurs after the development and/or revisions to the plan of care have been finalized and

[221] Centers for Medicare & Medicaid Services. (2022, April 15). *Care Planning Guidance for PACE Organizations.* Retrieved from Silo Tips: *https://silo.tips/download/care-planning-guidance-for-pace-organizations (pg 11).*

implemented by the IDT. In the 1999 PACE interim final rule (64 FR 66252), CMS specifically stated that plans of care must be developed, reviewed, and reevaluated in collaboration with the participants or caregivers. The purpose of participant/caregiver involvement is to ensure that they approve of the care plan and that participant concerns are addressed. Furthermore, in the 2006 PACE final rule (71 FR 71293), CMS reiterated that it is our expectation that the IDT will include the participant in the plan of care development when possible and include the participant's representative when it is not appropriate to include the participant or at the instruction of the participant. We continue to believe that participant and caregiver involvement in the development, review, and reevaluation of the plan of care is necessary to ensure participants' needs are fully met.

As a result of our experience overseeing PACE organizations, we believe it is prudent to implement additional requirements related to the minimum requirements for a participant's plan of care, including: further defining the timeframes for care plan development and reevaluation, defining the minimum content that should be reflected in a plan of care, emphasizing the ongoing responsibilities of the IDT to monitor and revise the plan of care to determine its effectiveness, and defining the involvement of the participant and/or their caregiver in the plan of care before it is finalized. In developing these proposed requirements, we attempted to adopt language and requirements that are consistent with the long-term care facility regulation at § 483.21(b), when possible. The regulation at § 483.21(b) requires nursing facilities to develop comprehensive and person-centered care plans that meet residents' needs and identify the services necessary to meet those needs. Individuals who enroll in PACE must be deemed as nursing home eligible; therefore, individuals who enroll in PACE and individuals who receive services from nursing facilities have similar needs. Additionally, while PACE organizations are insurers, they are also direct care providers. Since nursing homes are also direct care providers, and serve a similar population, aligning care planning requirements across these programs is an important safeguard for participants, and will improve the PACE organization's ability to meet participants' needs and to deliver necessary services for this vulnerable population.

First, we propose to modify the requirement in § 460.106(a) to require that the members of the IDT specified in § 460.102(b) must develop, evaluate, and if necessary, revise a person-centered plan of care for each participant. This is consistent with the requirement at § 460.104(b) that states that within 30 days of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire IDT. Additionally, the IDT is required to reevaluate the plan of care on a semi-annual basis at the current § 460.106(d); however, we are proposing to remove that requirement as our proposal at § 460.106(a) would cover the role of the IDT in both the initial care plan development and also the subsequent reviews and reevaluations of the care plan. We are also proposing to add language into § 460.106(a) that would require each plan of care to take into consideration the most current assessment findings and identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being. As we will discuss in Section VI.J. of this proposed rule, since PACE is a direct care provider, serving nursing home eligible participants, we also considered nursing home regulations as we drafted this proposal. The nursing home regulations require that care plans must describe ''the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psych-social well-being'' (§ 483.21(b)(1)(i)). This language should also apply to PACE care plans, since they serve the same nursing home eligible population.

Next, we propose to add a new section, § 460.106(b), which would define the specific timeframes for developing, evaluating, and revising care plans. For initial care plans, we intend to maintain the requirement for the IDT to finalize the development of the initial plan of care within 30 calendar days of the participant's enrollment that is located at current § 460.106(a), but we propose to move this requirement to new section § 460.106(b)(1).

The regulation at § 460.106(d) currently requires the IDT to reevaluate the plan of care, including defined outcomes, and make changes as necessary on at least a semi-annual basis. The interpretation of the semi-annual timeframe has posed issues for PACE organizations. We therefore propose at § 460.106(b)(2) to require that the IDT must complete a reevaluation of, and if necessary, revisions to each participant's plan of care at least once every 180 calendar days. We believe that creating a strict timeframe of 180 days would be less ambiguous and easier for organizations to track.

We propose at § 460.106(b)(3)(i) that the IDT must complete a reevaluation, and if necessary, revisions of the plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status or more expeditiously if the participant's condition requires. Currently, the members of the IDT specified in § 460.104(d)(1) must conduct reassessments when a participant experiences a change in participant status. Additionally, the IDT members that conduct a reassessment must also reevaluate the participant's plan of care (see § 460.104(e)(1)) and discuss any changes in the plan with the IDT (see § 460.104(e)(2)). However, there is no timeframe for how quickly the IDT members must conduct those reassessments or reevaluate the plan of care to determine if changes are needed. We believe that a 14-calendar day timeframe is appropriate since it will ensure the IDT is promptly acting on changes to the participant's status. In considering an appropriate timeframe, we reviewed the nursing home requirements. The long-term care regulations at § 483.20(b)(2)(ii) require that the resident receive a comprehensive assessment within 14 calendar days after the date the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. The long-term care facility must then use the results of the assessments to develop, review and revise the resident's comprehensive plan of care (see § 483.20(d)). This is an appropriate standard to apply in PACE as well, since as we have previously discussed, participants in PACE are deemed nursing home eligible, and therefore their conditions are substantially similar to the conditions a nursing home resident experiences. As discussed later in this section of this proposed rule, we are also proposing to modify § 460.104(e) to emphasize that all required assessments must be completed prior to the plan of care being revised. Therefore, this 14-calendar day timeframe would include both the required assessments under § 460.104(d)(1) and the process of revising the plan of care under § 460.106.

We propose to specify at § 460.106(b)(3)(i) that the 14-calendar day timeframe starts when the PACE organization determines, or should have

determined, that a change in the participant's condition occurs. This requirement would align with long-term care regulations for when the timeframe begins following a participant's (or resident's) change in condition. If a participant experiences a change in status that triggers this reassessment and reevaluation of the care plan, the PACE organization should not be able to delay the timeframe by not recognizing the change in status for a period of time. We also propose to define at § 460.106(b)(3)(i) what constitutes a change in status. While the PACE regulations require assessments when a change in participant status occurs, what constitutes a change in status has not been previously defined. Like other proposed changes in this proposed rule, we are proposing to adopt in PACE the requirement applicable to nursing homes at § 483.20(b)(2)(ii), but we have tailored the language of the proposed regulation to be specific to PACE. For example, the proposed PACE regulation would refer to the ''participant'' as opposed to the ''resident'', which is the term used in the long-term care regulation, it would use the phrase ''change in participant status'' where the long-term care regulation uses the phrase ''significant change''. Therefore, the requirement as proposed would state that for purposes of this section, a ''change in participant status'' means a major decline or improvement in the participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status, and requires IDT review or revision of the care plan, or both. The proposed change would bring additional consistency between the PACE and nursing home requirements and ensure similarly situated beneficiaries are treated equally.

In conjunction with the proposed requirement that a PACE organization must reevaluate and, if necessary, revise the plan of care within 14 calendar days after a change in the participant's condition occurs, we propose at § 460.106(b)(3)(ii) that if a participant is hospitalized within 14 calendar days of the change in participant status, the IDT must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital. We recognize that when a participant is hospitalized, it is difficult for the IDT to assess the participant, and revise a plan of care, during the course of that hospitalization. Given this complexity, we propose that the timeframe for reevaluating the plan of care starts when the participant is discharged from the hospital. Despite this proposed exception, we would remind PACE organizations that their responsibilities toward the participant do not end or stop when a participant is hospitalized, and the IDT should remain alert to pertinent information in all care settings under § 460.102(d)(2)(ii).

We solicit comment on whether 14 calendar days is an appropriate timeframe to use. We also considered 21 or 30 calendar days, but were not persuaded to propose either, given the 14-day requirement in the nursing home regulations. However, are interested in commenters' feedback on whether 21 or 30 days would be more appropriate and, if so, why the timeframes for PACE and nursing homes should be different.

We propose at § 460.106(c) to make certain modifications related to the content of a plan of care. Currently, the content of a plan of care is specified at § 460.106(b), which requires the care plan to include the care needed to meet the participant's medical, physical, emotional and social needs; identify measurable outcomes to be achieved; utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal; identify each intervention and how it will be implemented; and identify how each intervention will be evaluated to determine progress. We have seen as part of our audit and oversight activities where treatments for participants' medical conditions are included in discipline-specific notes, but not in the comprehensive care plan. This has resulted in members of the IDT being unaware of what treatments or recommendations the participant has received from different members of the IDT or from outside contracted specialists. As a result, we have seen participants experience delays in receiving the recommended treatment or service, the treatment or service not being provided at all, and in some situations, duplicate orders for a service or treatment due to the IDT being unaware the service or treatment was previously provided. Therefore, in addition to proposing to move the content of plan of care requirements from § 460.106(b) to § 460.106(c), we propose to add language to the section to create minimum requirements for what each plan of care must include. When determining the minimum content a plan of care should include, we considered the care plans that nursing homes are required to create. Specifically, we considered the regulations at § 483.21(b) which specify the requirements for a comprehensive plan of care. Additionally, § 483.21(b) makes reference to § 483.24 (Quality of Life), § 483.25 (Quality of Care), and § 483.40 (Behavior Health), so we considered those sections as well. Given the similarities between PACE participants and nursing home participants, our proposal aligns with the nursing home requirements to the extent we believe those requirements are applicable. Therefore, at § 460.106(c), we propose modifying the language to state at a minimum, each plan of care must meet certain requirements, which would be set forth in the regulations at proposed § 460.106(c)(1)(i) through (xiii). At § 460.106(c)(1), we propose to add language that requires PACE organizations to identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring, and that at a minimum, the care plan must address specific factors we will discuss in the next paragraph. Care plans are currently required at § 460.106(b)(1) to include the care needed to meet the participant's medical, physical, emotional and social needs, as identified in the initial comprehensive assessment. However, we are proposing to further specify that the plan of care should address all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring. This is consistent with nursing home requirements since nursing homes must assess a resident's disease diagnoses and health conditions as part of the comprehensive assessment (see § 483.20(b)(1)(x)) and use those assessments in developing, reviewing and revising the plan of care (see § 483.20(d)). We believe our proposal related to chronic behavioral and psychiatric disorders is consistent with long-term care requirements in § 483.40, which require that each resident must receive and the facility must provide the necessary behavioral health care and services. As we mentioned earlier, the nursing home care plan requirements at § 483.21(b) reference the behavior health requirements at § 483.40. Therefore, we propose that chronic behavioral and psychiatric disorders that require treatment or routine monitoring also be included in PACE plans of care.

While the nursing home assessment criteria require consideration and assessment of all disease diagnoses and health conditions, we are proposing in PACE to limit what diseases must be included in the plan of care to those that are chronic and require treatment or routine monitoring. For example, if a participant had Hepatitis C but was treated and cured, that disease may not need to be included in the plan of care. On the other hand, if a participant has coronary artery disease and requires ongoing monitoring by a cardiologist, we would expect that disease to be included in the plan of care. When considering how organizations would define ''chronic'' we believe that most organizations would consider the guidance issued by the CDC, which defines chronic diseases as conditions that last 1 year or more, and require ongoing medical attention or limit activities of daily living or both.[222] We also considered whether it would be appropriate for the plan of care to address acute conditions, but decided that including acute conditions could make the care plan subject to more modifications than what is feasible for the IDT. For example, if the care plan needed to be updated for every infection, the care plan may be under a constant state of revision. However, we solicit comment on whether acute conditions should be included in the minimum content that a care plan must address.

We propose to specify at § 460.106(c)(1)(i) that the PACE participant's plan of care must address the participant's vision needs. This is consistent with the long-term care provisions at §§ 483.20(b)(1)(v) and 483.25(a). Given the age of the PACE population, and the co-morbidities that may impact this population (such as diabetes), addressing a participant's vision needs is an important part of any plan of care. We similarly propose at § 460.106(c)(1)(ii) that a PACE participant's plan of care must address the participant's hearing needs. This is consistent with the long-term care regulations at § 483.25(a). We propose at § 460.106(c)(1)(iii) that a participant's plan of care must address the participant's dentition. This would be consistent with the requirement at § 483.20(b)(1)(xi). We propose at § 460.106(c)(1)(iv) that a plan of care must address the participant's skin integrity. This requirement would be consistent with the requirements at §§ 483.20(b)(1)(xii) and 483.25(b). We propose at § 460.106(c)(1)(v) that the participant's plan of care must address the participant's mobility. This requirement would be consistent with the requirement at § 483.25(c). We propose at § 460.106(c)(1)(vi) that the participant's plan of care must address the participant's physical functioning (including activities of daily living). This would be consistent with the requirements at §§ 483.20(b)(1)(viii) and 483.24(b). We propose at § 460.106(c)(1)(vii) that the plan of care must address the participant's pain management needs. This would be consistent with the requirement at § 483.25(k).

The next few proposed requirements deviate from the nursing home requirements and are tailored specifically to the PACE program. We propose to require at § 460.106(c)(1)(viii) that the plan of care address the participant's nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs. This proposed language is based on the long-term care regulations at §§ 483.20(b)(1)(xi), 483.24(b)(4), and 483.25(g), but it is tailored to be more specific to PACE. In a nursing facility, the facility is responsible for providing three meals a day in the actual facility, and therefore the access to meals is not as much of an issue. However, in PACE, participants live in a variety of settings. While the PACE organization is responsible for ensuring that participants' nutritional needs are met per the regulations at § 460.78, the exact manner in which the organization meets that requirement may be different for each participant. As we stated in the 2006 PACE final rule (71 FR 71281), the PACE organization is responsible for a participant's health and safety including his or her nutritional needs 24 hours a day, 7 days a week. The IDT must assess the participant's needs as well as his or her access to adequate nutrition. The participant's nutritional requirements and dietary needs should be included in the plan of care, whether it is providing tube feedings, arranging for Meals on Wheels, sending meals home with the participant, or documenting that appropriate meals are provided by the family/caregiver. For this reason, we are including in proposed § 460.106(c)(1)(viii) language that would specify that the plan of care address not only nutrition, but also how a participant accesses meals that meet their nutritional and special dietary needs.

We propose at § 460.106(c)(1)(ix) to establish the requirement that the plan of care address the participant's ability to live safely in the community, including the safety of their home environment. This proposal also deviates from the nursing home requirements, as the goal of PACE is to keep nursing home eligible individuals out of a facility and living in the community. In order to accomplish that goal, the IDT must assess the participant's environment and living situation for potential factors that may make it not safe for the participant. For example, if the PACE organization recognizes the participant does not have a means of contacting either the PACE organization or emergency services, the PACE organization should address that concern as part of the plan of care, and provide the participant with a method of contacting those individuals or entities. As we noted in the 2006 PACE final rule (71 FR 71275), PACE organizations are at risk for all health care services the participant receives and; therefore, we expect PACE organizations will be involved in assuring the health and safety of participants at all times, including when they are at home. We propose at § 460.106(c)(1)(x) that the plan of care must address the participant's home care needs. This proposal would also deviate from nursing home guidance; however, we believe it to be important in the PACE model. The nursing home is responsible for 24-hour care similar to PACE, but inherently provides all care as part of the resident living at the facility. PACE often provides similar care, for example medication administration, through home care services. Therefore, we believe a participant's home care needs must be addressed through the plan of care. We propose to establish at § 460.106(c)(1)(xi) that the participant's center attendance must be included in the plan of care. Again, while not a requirement in nursing homes, center attendance is an integral part of the PACE program, and we believe it is appropriate to include it in a participant's plan of care. We propose at § 460.106(c)(1)(xii) to require that a participant's transportation needs be incorporated into the plan of care. Transportation is an essential part of the PACE benefit, as often it is the PACE transportation that ensures participants have access to their necessary medical appointments and specialist visits. In addition, we propose to require at § 460.106(c)(1)(xiii) that a participant's communication needs (including any identified language barriers) be incorporated into the plan of care. For participants who are not English

[222] Centers for Disease Control and Prevention. (2022, May 6). About Chronic Diseases. Retrieved from: *https://www.cdc.gov/chronicdisease/about/index.htm.*

speaking, or have some other difficulty communicating, addressing and resolving these needs preemptively can mean the difference between quality of care and participant's not receiving the care they need.

We are soliciting comment on all items identified in the proposed § 460.106(c)(1) and whether they should be required content in a plan of care for PACE participants. Along with any general comments that are submitted, we are specifically requesting comment on whether to include acute diseases and/or acute behavioral and psychiatric disorders in the plan of care. We contemplated adding acute diseases as part of the minimum criteria for the plan of care, but ultimately, we believe it might be hard to operationalize. When submitting comments on whether acute diseases should be included in the plan of care, we ask that commenters also indicate whether they believe the term ''acute diseases'' should be defined in the PACE regulations, and if so, how. We also solicit comment on whether there is other content that is required to be in a nursing home care plan that should also be included in a PACE plan of care. We are particularly interested in feedback that addresses whether we should include incontinence care and dialysis care as required content for PACE plans of care. (Both incontinence care and dialysis care are required in nursing home care plans, per the regulations at § 483.25(e) and (l)).

We propose at § 460.106(c)(2) to require that the plan of care must identify each intervention (the care or service) needed to meet the participant's medical, physical, emotional, and social needs. In addition to identifying the needs of the participant as they relate to the proposed criteria in § 460.106(c)(1), the PACE organization must also identify any service that will be provided in response to those needs. PACE organizations are currently required at § 460.106(b)(4) to identify each intervention, so this provision is consistent with the current requirement, but further emphasizes that it's any intervention needed to meet the participant's medical, physical, social or emotional needs. For example, if the participant has poor vision, the IDT may deem it necessary to provide glasses and routine trips to the optometrist or ophthalmologist. The IDT would need to identify these services in the plan of care. We propose to include at § 460.106(c)(2) an exception to the interventions that need to be included in the plan of care; specifically, proposed § 460.106(c)(2) would provide that the plan of care does not need to identify the medications needed to meet a participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record. As we define services at § 460.6 to include medications, we strongly believe that medications are an important part of the PACE benefit, and may be the most applicable service for a particular diagnosis or condition. However, we also understand that medications may change frequently, especially when a participant is first beginning a medication routine, and are typically documented in the medical record in way that would allow the IDT to understand all current, pending and discontinued medications; therefore, we are not inclined to require medications to be included in the plan of care. However, while we are not proposing to require that all medications be identified in the plan of care, nothing would prohibit an organization from choosing to include medications in the care plan. We are soliciting comment on this proposal and whether the plan of care should include a comprehensive list of active medications.

We propose to redesignate current § 460.106(b)(3), which requires the care plan to utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome, as § 460.106(c)(3).

We propose at § 460.106(c)(4) to specify that the plan of care must identify how each service will be implemented, including a timeframe for implementation. The IDT is already required to identify how each intervention will be implemented in § 460.106(b)(4), however we are proposing to modify the language to specify that as part of identifying how the intervention will be implemented, the PACE organization should specify a timeframe for that implementation. As part of the plan of care process, the IDT should determine the parameters of a service, specifically how it will be provided to the participant in order to meet their needs. For example, it is not enough for the IDT to decide that the participant needs physical therapy. They should also discuss how often the participant should receive physical therapy, when it should be provided, and by whom.

We propose at § 460.106(c)(5) to require that the plan of care must identify a measurable goal for each intervention. The current care plan regulations require that the plan identify measurable outcomes (§ 460.106(b)(2)), and utilize appropriate interventions that advance the participant toward a measurable goal (§ 460.106(b)(3)). Our proposal at § 460.106(c)(5) is consistent with the intention of the current requirement; however, we believe the specificity of identifying measurable goals for each service are necessary. We believe that it is important when identifying a service to also identify the measurable goal for that service. Using the aforementioned example of physical therapy, we believe the IDT must determine what measurable goal the participant should achieve as a result of attending physical therapy. For example, the goal may be the participant's increased mobility demonstrated by the participant ambulating a specific distance either determined by an actual measurement (for example, 100 feet) or from one area of a room to another (for example. the participant will ambulate from the bed to the toilet without falling).

We propose at § 460.106(c)(6) to require that the care plan identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified. The IDT is currently required at § 460.106(b)(5) to identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes. While our proposal is similar in intent, it would reduce ambiguity by specifying that the evaluation by the IDT should be focused on whether the goal was met for determining whether the intervention needs to be continued, discontinued or modified. For example, the IDT determines that the PACE participant should receive physical therapy 3 times a week. The goal may be that the participant is able to ambulate independently 100 feet. The IDT may determine the appropriate timeframe for that goal is 6 weeks. At the time the PACE organization identifies the measurable goal, it must determine how it will evaluate the participant's success in meeting the goal. In this example, at the end of the 6-week timeframe, the PACE organization should have a mechanism to determine if the participant has met the goal of ambulating 100 feet. If the participant met the goal, the IDT may determine the intervention can be discontinued. If the participant has not met the goal, the IDT may determine whether the intervention needs to be modified or if it should be continued for another set period of time, at which point the IDT will need to determine a new measurable goal and how it will be evaluated.

Finally, we propose at § 460.106(c)(7) to require that the plan of care must identify the participant's preferences and goals of care. It is important for the PACE organization to document the

participant's goals and wishes for treatment and to consider them not only when developing and reevaluating the plan of care, but during implementation of the services that were added to the plan of care.

Currently, § 460.106(c) includes requirements for the implementation of the plan of care. We propose to move these requirements to § 460.106(d) and make modifications to the existing requirements. Currently, § 460.106(c)(1) requires the team to implement, coordinate, and monitor the plan of care regardless of whether the services are furnished by PACE employees or contractors. We propose to move this language to § 460.106(d)(1) and to modify it to read that the IDT must continuously implement, coordinate, and monitor the plan of care, regardless of whether the services are furnished by PACE employees or contractors, across all care settings. Through our audit and oversight activities, we have seen where PACE organizations met the minimum requirement of reassessing participants semiannually and updating the plan of care accordingly, but then took no further action with respect to the plan of care until the next semiannual assessment period. We want to reemphasize that the intent of the plan of care is to create a comprehensive, living document that is updated per the participant's current status at any given point; we are proposing to add the word ''continuously'' to emphasize that the team must continue to be responsible for implementing, coordinating and monitoring the plan of care. We are proposing to include language specifying that this implementation, coordination and monitoring of the plan of care must be done across all care settings, to reiterate the responsibilities of the IDT in ensuring that care is appropriately coordinated and furnished, regardless of where a participant resides. For example, if a participant is living in a nursing home, that does not absolve the IDT of its responsibility to ensure that the care is implemented appropriately and that the participant's needs are met.

Currently, § 460.106(c)(2) requires the IDT to continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the IDT. We propose to move the current requirements at § 460.106(c)(2) to § 460.106(d)(2) and to modify § 460.106(d)(2) to specify that the IDT must continuously evaluate and monitor the participant's medical, physical, emotional, and social needs, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the IDT and other employees or contractors. The proposed modification to change the language from ''participant's health and psychosocial status'' to ''participant's medical, physical, emotional, and social needs'' is intended to align more closely with the regulation on required services at § 460.92(b).

We propose to add § 460.106(d)(3) to state that all services must be arranged and provided in accordance with § 460.98(c). The provision of care planned services is an important part of implementing the plan of care. As we discussed in section VI.G. of this rule, we have proposed additional criteria concerning the arranging and provision of services that are determined necessary by the IDT. When a service is care planned, the IDT has determined that the service is necessary for the participant, and we would expect it to be arranged and provided in accordance with the rules governing other approved or necessary services.

Currently, § 460.106(e) requires that the team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed. We have seen as part of our audit and oversight activities where participants and/or caregivers are unaware of the contents of their plan of care or what services they should be receiving. We have also seen that the involvement of the participant and/or caregiver in the plan of care is often limited, and often reflects no direct involvement or input in that decision-making process. Instead, we often see that the plan of care is finalized by the team and then provided or reviewed with the participant after the fact as a means of ''collaboration.'' Therefore, we propose to split the existing language into two new paragraphs § 460.106(e)(1) and (e)(2). We propose at § 460.106(e)(1) that the IDT must develop, evaluate, and revise each plan of care in collaboration with the participant or caregiver, or both. We are proposing to amend the language to refer to ''each'' plan of care in order to emphasize that this collaboration must be performed for every new plan of care, including the initial, semi-annual, and a revised plan of care as a result of a change in status. We also propose at § 460.106(e)(2) that the IDT must review and discuss each plan of care with the participant and/or caregiver before the plan of care is completed to ensure that there is agreement with the plan of care and the participant's concerns are addressed. We want to ensure the participant and/or caregiver has an opportunity to voice concerns and ensure that any concerns are addressed in the proposed plan of care; therefore, our proposal addresses the expectation that the IDT discuss the plan of care with the participant prior to it being finalized. We believe a discussion about the plan of care, with the participant and/or caregiver, is the best way for the IDT to explain the care they believe is necessary, and receive input from the participant and/or caregiver about their wishes and concerns related to their care.

Currently, § 460.106(f) requires that the team must document the plan of care, and any changes made to it, in the participant's medical record. As part of our audit and oversight activities, we have seen organizations have insufficient documentation related to participant plans of care. We often see minimum documentation related to whether a participant has met the goals set at the last assessment and any changes in the participant's status, but we do not see documentation of the conversations with the participant in the plan of care, including whether the participant disagreed with any part of the plan of care and whether those concerns were addressed. Therefore, we propose to modify the language in § 460.106(f) to state that the team must establish and implement a process to document and maintain records related to all requirements for the plan of care in the participant's medical record, and ensure that the most recent care plan is available to all employees and contractors within the organization as needed. This proposal is consistent with the current requirement, but ensures that the PACE organization understands that it must document all care planning requirements. Therefore, we would expect to see documentation that the appropriate members of the IDT were involved in care planning in accordance with § 460.106(a), the IDT met the timeframes for finalizing care plans in § 460.106(b), that the care plans included all required content in § 460.106(c), that the IDT implemented and monitored the plan of care in accordance with § 460.106(d), and that the participant and caregiver were appropriately involved in the care planning process in accordance with § 460.106(e).

We also propose certain modifications to § 460.104 to align with our proposed amendment to § 460.106. Currently,

§ 460.104(e) requires that the team member who conducts a reassessment must reevaluate the participant's plan of care, discuss any changes in the plan with the IDT, obtain approval of the revised plan from the IDT and the participant (or designated representative), and furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires. We propose to remove most of the language currently in section § 460.104(e), and add the requirement that when the IDT conducts semiannual or unscheduled reassessments, the IDT must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments. We believe this will eliminate any unnecessary duplication and ensure there is no confusion as it relates to care plans.

As both the development of and updates to the care plan are a typical responsibility for the IDT, any burden associated with this would be incurred by persons in their normal course of business. Therefore, the burden associated with the development of and updates to the care plan are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and is a usual and customary business practice.

J. Specific Rights to Which a Participant Is Entitled (§ 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 considerate, respectful care and the right not to be discriminated against (§ 460.112(a)); the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions (§ 460.112(b)); the right to access emergency services without prior authorization (§ 460.112(d)); and the right to participate fully in decisions related to his or her treatment (§ 460.112(e)).

In this proposed rule, CMS is proposing to amend § 460.112 to incorporate the following participant rights: the right to appropriate and timely treatment for health conditions including the right to receive all care and services needed to improve or maintain the participant's health condition and to attain the highest practicable physical, emotional and social well-being; the right to have the PACE organization explain all treatment options; the right to be fully informed, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services; the right to fully understand the PACE organization's palliative care, comfort care, and end-of-life care services; and the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121.

Sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act establish that PACE organizations shall provide enrollees access to necessary covered items and services 24 hours per day, every day of the year. CMS codified these required services at § 460.92, which provides that the PACE benefit package for all participants, regardless of the source of payment, must include all Medicare covered services, all Medicaid covered services as specified in the State's approved Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participant's overall health status. At § 460.98(a), CMS established the requirement for PACE organizations to provide care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year. However, through our audit and oversight activities, we have identified some PACE organizations that do not provide care meant to improve or maintain the participant's condition, and instead provide a palliative-like benefit, where the services provided to participants are geared more toward ensuring the participant's comfort even when that is not in line with the participant's wishes or needs. We have also seen organizations, in care plans and notes from discussions with participants, use terms such as palliative care and comfort care without clearly defining those terms for the participants and/or their designated representatives, leaving participants and families confused as to what level of care they are receiving. Based on what we have seen through audits, we believe that not all participants understand that they are entitled to all care and services deemed necessary to improve or maintain their health status, and are not limited to services related to palliative, comfort or end-of-life care. As we stated in the January 2021 final rule (86 FR 6041), 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. Therefore, it is reasonable that a PACE participant may transition from receiving treatment meant to cure or maintain health conditions at the time of enrollment, to receiving end-of-life care by the time they approach their death. However, it is essential that PACE participants understand their right to receive all treatments in the PACE benefit package that are necessary and appropriate at the time of enrollment and on an ongoing basis, and that they clearly understand their rights as they transition from receiving treatment focused on curing a condition or improving or maintaining their health status, to treatment meant solely to provide comfort.

For the foregoing reasons, we are proposing certain modifications to § 460.112. First, we propose to redesignate current paragraphs (a) through (c) as paragraphs (b) through (d) to allow for the addition of proposed new paragraph (a). Proposed new paragraph (a)(1) would state that participants have a right to appropriate and timely treatment for their health conditions, which includes the right to receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being. We are proposing to add this language in new paragraph (a)(1) of § 460.112 because the right to treatment is a separate and distinct right that should be assigned its own paragraph in the participant rights section. By creating a new paragraph (a) and titling it the right to treatment, we aim to emphasize the participant's right to receive care and services, which many of the other participant rights relate to or build upon. In drafting proposed new § 460.112(a)(1), we considered the language in § 460.92 related to services meant to improve or maintain the participant's health condition. Additionally, since a PACE organization is a direct care provider that serves nursing home eligible participants, we also considered nursing home regulations as we drafted this proposal. The nursing home regulations require that care plans must describe ''the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being'' (§ 483.21(b)(1)(i)). We adapted this language to align with existing PACE regulations. We believe this modification will ensure that PACE participants are made aware of their

right to receive any care and services that are necessary to improve their condition to the highest practicable level, or maintain their condition to the highest practicable level, depending on the participant's health condition.

In addition, we propose to add to § 460.112 a new paragraph (a)(2), which would state that participants have the right to appropriate and timely treatment for their health conditions, including the right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team. The right to access emergency care services currently appears at § 460.112(d); however, we believe that it relates to the right to treatment, and therefore, we propose to move the text of current § 460.112(d) to new § 460.112(a)(2). It is appropriate that both of the proposed provisions concerning the right to treatment (that is, proposed paragraph (a)(1) regarding standard treatments and proposed paragraph (a)(2) regarding emergency treatments) appear in the same paragraph of § 460.112.

In the 1999 PACE interim final rule, CMS codified at § 460.112(a) (which we propose to redesignate as § 460.112(b)) that all participants have the right to considerate respectful care, and each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment (64 FR 66253). CMS also codified at § 460.112(e) the right of participants to participate fully in all treatment decisions. As part of that right, participants have the right to have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions (§ 460.112(e)(1)). This right has two specific parts; the right to have all treatment options explained in a culturally competent manner, and the right to make health care decisions. We believe the first right, the right to have all treatment options explained in a culturally competent manner, relates more to the rights under redesignated § 460.112(b) (''Respect and nondiscrimination''). Therefore, we propose to add a new paragraph at § 460.112(b)(8) which states that participants have the right to have all information regarding PACE services and treatment options explained in a culturally competent manner. Culturally competent care respects diversity in the patient population and cultural factors that can affect health and health care, and can contribute to the elimination of racial and ethnic health disparities. By moving the provision establishing the right to have treatment options explained in a culturally competent manner from § 460.112(e)(1) to new § 460.112(b)(8), as proposed, we would emphasize that receiving materials about all PACE services, not just treatment options, in a culturally competent manner is an inherent right.

In the 1999 PACE interim final rule (64 FR 66254), CMS codified the participant's rights to receive accurate and easily understood information at current § 460.112(b) (which we propose to redesignate as § 460.112(c)). In the 2006 PACE final rule, CMS further stated that this information was necessary for participants to ''comprehensively assess differences in their health care options'' (71 FR 71295). CMS also codified at § 460.112(e) that ''a participant who is unable to participate fully in treatment decisions has the right to designate a representative'' (64 FR 66290). For the participant's designated representative to be able to act on behalf of the participant in the event the participant is unable to make informed decisions, the designated representative should receive the same accurate, easily understood information the participant receives. Therefore, we are proposing to add language to the newly designated § 460.112(c) that would provide that a participant has the right to have all information in this section shared with their designated representative. As previously mentioned, participants may be enrolled with a PACE organization until their death, and therefore the PACE benefit adapts as the participant's needs change. Because PACE is designed to meet a participant's needs, regardless of what those needs are, PACE organizations are permitted to provide participants similar benefits to hospice or end-of-life care while allowing participants to remain in PACE, assuming that is in line with the participant's wishes for treatment. However, we have seen as part of our audit and oversight activities that certain types of care offered by PACE organizations are not well-defined. For instance, through audits we have seen organizations use terms such as palliative care, comfort care, and end-of-life care, with little or no information on what those terms mean or how they are defined or implemented across PACE organizations. We have also seen that the lack of a clear, comprehensive definition of palliative care, comfort care, or end-of-life care has caused confusion to participants and/or their caregivers related to what care they are and are not getting when this type of care is provided. While CMS does not seek to define these terms, we believe it is important for PACE organizations to define the terms within their respective programs, and provide clear information to participants and their designated representatives on what the terms mean. Participants and their representatives have the right to understand how their choices to pursue these different types of treatment options will impact their ability to continue pursuing care and services meant to improve or maintain their health conditions. Therefore, we are proposing to add language to newly designated § 460.112(c)(5) that would provide that participants have the right to be fully informed, in writing, of several factors before the PACE organization implements palliative care, comfort care, or end-of-life care. We propose that the written notification to participants must explain four different aspects of the treatment options, which we outline in proposed § 460.112(c)(5)(i) through (iv).

First, we propose at § 460.112(c)(5)(i) that the written notification must include a description of the palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving to meet their individual needs. The explanation of the different types of care, and more importantly, how they differ from the care being currently received is important in ensuring that participants are fully informed of their options for treatment and are therefore able to make informed decisions on the care they wish to receive. A participant should have the right to fully understand the care they are agreeing to receive prior to that care being initiated.

Proposed § 460.112(c)(5)(ii) would require PACE organizations to explain, in writing, to participants or their designated representative whether palliative care, comfort care, or end-of-life care services (as applicable) will be provided in addition to or in lieu of the care the participant is currently receiving. We have seen through audit that some PACE participants receive palliative care and/or comfort care in addition to other services a participant may be receiving, including services meant to improve or maintain their health condition. We have also seen PACE participants receive palliative care and/or comfort care instead of providing services meant to improve or maintain the participant's health condition. In other words, for some participants, when they agree to receive palliative care or comfort care, they are also agreeing to no longer receive care

meant to improve or maintain their health condition and are receiving, in essence, end-of-life care. While this may be appropriate in some instances, given a participant's condition, it is important that participants fully understand what they are agreeing to when they enter into palliative or comfort care status. We believe that part of the appeal of PACE to participants is the person-centered nature of the benefit, which allows for the IDT to provide any and all services that are tailored around the participant's needs. This is true for end of life services too. One participant may want, and the IDT may approve, comfort measures in addition to treatment meant to maintain the participant's health condition. Another participant may be at the end of their life, and may only want treatment meant to reduce or control pain. CMS believes that the PACE organization is allowed to pursue either scenario, but that the participant must be able to understand the options and what care they will or will not receive in order to make an informed decision.

Proposed § 460.112(c)(5)(iii) would require PACE organizations to identify all services that would be impacted if the participant and/or their designated representative elects to initiate palliative care, comfort care, or end-of-life care. For example, one or more of the following types of services could be impacted and the PACE organization should include the impacted services in the detailed description: physician services (including specialist services), hospital services, long-term care services, nursing services, social services, dietary services, transportation, home care, therapy (including physical, occupational, and speech), behavioral health, diagnostic testing (including imaging and laboratory services), medications, preventative healthcare services, and PACE center attendance. Under this proposal, PACE organizations would be required to provide a detailed explanation of how specific services would be impacted by the addition of or transition to palliative care, comfort care, or end-of-life care. If the participant would be receiving palliative care or comfort care in addition to all the other services they are currently receiving, then the PACE organization may not have to provide a detailed analysis, and could simply include language that the designation of palliative care or comfort care will not impact any existing services. However, if moving a participant to palliative care, comfort care, or end-of-life care would impact their services (for example a participant would no longer be sent to specialists, or they would no longer be sent to the hospital), then a PACE organization would be required to identify the services that would be impacted, and explain how those services would be impacted.

Proposed § 460.112(c)(5)(iv) would state that the participant has the right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason either verbally or in writing. We also propose to require PACE organizations to explain this right to participants both orally and in writing. A participant has the right to fully participate in treatment decisions, as established at current § 460.112(e). Part of that right is participating in the decision-making process of what care to receive, and a participant must not only understand what the proposed care or treatment decisions mean, but also that they can change their mind with regards to treatment decisions previously made. We have seen through audits and oversight activities that participants or their designated representatives may decide to pursue palliative care or comfort care, without fully understanding what those terms mean. We have also seen situations where participants or their designated representatives want to stop palliative care or comfort care when they realize they will no longer receive other services and do not know they have the right to revisit prior treatment decisions. Participants should be clearly informed, in writing, that they have the ability to change their mind on these important treatment decisions.

In the 1999 PACE interim final rule (64 FR 66255), CMS established at § 460.112(e) the right for each participant to fully participate in all decisions related to his or her care. Paragraph (e)(1) specifies that this includes the right ''[t]o have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.'' In this proposed rule, we are proposing to modify the language in § 460.112(e)(1) by removing the language regarding the participant's right to have all treatment options explained in a culturally competent manner. As we explained in the discussion around our proposed amendments to § 460.112(b), the right to have treatment options explained in a culturally competent manner is better suited for inclusion in that paragraph, which, as amended, sets forth participant rights related to respect and non-discrimination. We also propose to restructure and modify § 460.112(e)(1) by separating the requirements into three subparts at § 460.112(e)(1)(i), (ii) and (iii). We propose at § 460.112(e)(1)(i) to establish that participants' right to make health care decisions includes the right to have all treatment options fully explained to them. Inherent in the right to participate in health care decisions is the right to understand all available options for treatment. A participant cannot make an informed health care decision without fully understanding the options available. Proposed § 460.112(e)(1)(ii) would provide that participants have the right to refuse any and all care and services. As we explained in the 2006 PACE final rule (71 FR 71298), the right to refuse treatment is a type of health care decision, and participants have the right to make those decisions. We propose at § 460.112(e)(1)(iii) to specify that participants have the right to be informed of the consequences their decisions may have on their health and/or psychosocial status. The language at current § 460.112(e)(1) refers to the participant's right to ''be informed of the consequences of the decisions,'' but we propose to add additional specificity around that right and the obligation it creates for PACE organizations by modifying the regulatory language to refer to the participant's right to ''be informed of the consequences their decisions may have on their health and/or psychosocial status.'' We believe this proposed revision would emphasize that the participant should be made aware of how their decision to refuse care may impact their health and/or psychosocial status. For example, if a physician was recommending the participant have a diagnostic cardiac catherization, and the participant refused, the participant has the right to be informed that, by not having the diagnostic testing done, they might be at increased risk for a cardiac event, including a heart attack.

We propose to further amend § 460.112(e) by redesignating current paragraphs (e)(2) through (e)(6) as (e)(3) through (e)(7), and by adding a new paragraph (e)(2), which would state that participants have a right to fully understand the PACE organization's palliative care, comfort care, and end-of-life care services. Proposed paragraph (e)(2) would further require that PACE organizations take several steps, outlined at proposed § 460.112(e)(2)(i) through (iii), in order to ensure that participants understand this right. As we mentioned in our discussion of § 460.112(a), we have seen as part of our

audit and oversight activities that participants and/or their representatives are not always fully aware of what treatments they will or will not receive if they opt to pursue palliative care, comfort care, or end-of-life care services. While palliative care, comfort care, and ultimately, end-of-life care are necessary components of the PACE benefit, PACE organizations must ensure that participants fully understand these terms and treatment options, prior to them being initiated.

At § 460.112(e)(2)(i), we propose to establish that the PACE organization must fully explain the applicable treatment options to the participant prior to initiating palliative care, comfort care, or end-of-life care services. This proposal would require the PACE organization to explain to the participant what these terms mean, and how choosing one of those options would impact the participant's health. We are also proposing at § 460.112(e)(2)(ii) to require that the PACE organization provide the participant with written information about their treatment options in accordance with § 460.112(c)(5). In the discussion around § 460.112(c)(5), we highlighted that we believe providing written information on these terms is important for the participant, and that the information must include details regarding the treatment and how the participant's current services may be impacted. We are proposing to add paragraphs (e)(2)(i) and (e)(2)(ii) as separate provisions because the organization should be responsible both for providing the written notification outlined in § 460.112(c)(5), and actually explaining the treatment options in a way that is understandable to the participant. A participant may be overwhelmed by receiving only written notification; therefore, both provisions are necessary to ensure the participant has a full understanding of their options. Finally, we are proposing at § 460.112(e)(2)(iii) that the PACE organization obtain written consent from the participant or their designated representative to change a treatment plan to include palliative care, comfort care, or end of life care. Because some organizations stop treatments to improve or maintain a participant's condition when a participant enters palliative care or comfort care, it is especially important that participants or their designated representatives are in agreement with these treatment options, and consent to receiving this care. We believe ensuring that this consent is in writing is the most appropriate safeguard, not only for participants, but also for PACE organizations to ensure that they have adequate documentation to support providing these benefits. We propose to redesignate current paragraphs (e)(2) through (e)(6) of § 460.112 as (e)(3) through (e)(7) to allow for the addition of a new paragraph (e)(2) as discussed in this section. We want to emphasize that this proposed requirement would not take the place of any advanced directives a participant may have, and would not eliminate the requirement in current § 460.112(e)(2) (which would be redesignated as (e)(3) under our proposal) that requires a PACE organization to explain advance directives and to establish them, if the participant so desires. That directive is distinct from the notification proposed at new § 460.112(e)(2), which should explain the services under the PACE benefit that may be provided or not provided to the participant as a part of their care decisions.

In the 1999 PACE interim final rule (64 FR 66256, 66290), CMS codified at § 460.112(g) the participant's right to ''a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review.'' In the January 2021 final rule (86 FR 5864), CMS added § 460.121 to clearly define service determination requests and specify the requirements for how those requests would be processed. As we explained in that rule, the service determination request process serves an important participant protection, as it allows a participant to advocate for services (86 FR 6008). We also explained that the service determination request process is the first step of the appeals process (86 FR 6008). At § 460.112(g)(1), the participant is provided the right to be encouraged and assisted to voice complaints to PACE staff and outside representatives; and § 460.112(g)(2) provides participants the right to appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122. Because the participant rights in section § 460.112(g) discusses both the right to voice grievances and the right to appeal, it should also reference the right to request a service determination request, which is the first step in the appeals process. Therefore, we propose to add a new § 460.112(g)(2) to provide that a participant has the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121. We propose to redesignate current paragraph (g)(2) as (g)(3) to allow for the addition of a new paragraph (g)(2) as discussed in this section. We believe the burden associated with this provision is related to developing written templates regarding the PACE organization's palliative, comfort, and end-of-life care services and tailoring those templates to the participants. We discuss the burden in the collection of information section.

K. Grievance Process (§ 460.120)

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 have codified requirements around the processing of grievances at § 460.120. The grievance process serves as an important participant protection as it allows for participants and their family members to express complaints related to the quality of care a participant receives, or the delivery of services. Currently, § 460.120 defines a grievance as a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished. A PACE organization must have a formal written process to evaluate and resolve medical and nonmedical grievances by participants, family members, or representatives (§ 460.120(a)). At a minimum, the PACE organization's grievance process must include written procedures for the following: (1) how a participant files a grievance; (2) documentation of a participant's grievance; (3) response to, and resolution of, grievances in a timely manner; and (4) maintenance of confidentiality of a participant's grievance (§ 460.120(c)).

A PACE organization must discuss with and provide to the participant in writing the specific steps, including timeframes for response, that will be taken to resolve the participant's grievance. The PACE organization must also maintain, aggregate, and analyze grievance data for use in its internal quality improvement operations (§ 460.120(f)).

Since the grievance regulations were codified in 1999, CMS has received feedback from PACE organizations requesting clarification and guidance on the grievance process. Additionally, we have discovered through audits that the current grievance process, which allows PACE organizations latitude to define their own grievance resolution timeframes and develop their own procedures for processing grievances, has created confusion and inconsistency in how grievances are handled from organization to organization. We are

proposing certain modifications to the grievance requirements at § 460.120 to strengthen participant protections and provide more detailed processing requirements for grievances from PACE participants and their family members. We also propose certain adjustments that would align the requirements with the service determination process in § 460.121 for consistency.

Currently, the grievance requirements at § 460.120(a) require a PACE organization to have a formal written process to evaluate and resolve medical and nonmedical grievances by participants, their family members, or representatives. We propose to modify paragraph (a) of § 460.120 to align more closely with paragraph (a) of § 460.121, which establishes the requirement to have certain written procedures in place for identifying and processing service determination requests. First, we propose to amend § 460.120(a) by removing the current paragraph header, which reads ''Process to resolve grievances,'', adding in its place a new paragraph header, which would read, ''Written procedures.'' Specifically, we propose to modify the requirement to state that each PACE organization must have formal written procedures to promptly identify, document, investigate and resolve all medical and nonmedical grievances in accordance with the requirements in this part. It is important to ensure that PACE organizations develop internal processes and procedures to properly implement the grievance process. In addition, we propose to further amend § 460.120(a) by removing the list of individuals who can file a grievance, as we are proposing to create a new paragraph that outlines who may file a grievance at § 460.120(d).

We propose to add to § 460.120 a new paragraph (b), which would define a grievance in PACE as a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested; and further that a grievance may be between a participant and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant. Currently, the term grievance is defined in the introductory paragraph of § 460.120 as a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished. We have heard from PACE organizations over the years that they would prefer that the term grievance be better defined in the regulations, and we have received requests from PACE organizations for the grievance definition to be narrowed to exclude complaints that may not rise to the level of a grievance. Based on this feedback, we considered how we might refine the definition of grievance for purposes of PACE. In doing so, we reviewed how grievances are defined in other managed care programs and care settings, specifically in MA and in nursing homes.

The MA regulations define a grievance as any complaint or dispute, other than one that constitutes as organization determination, expressing dissatisfaction with any aspect of an MA organization's or provider's operations, activities, or behavior, regardless of whether remedial action is requested (§ 422.561). While the long-term care regulations do not define ''grievance'', § 483.10(j)(1) provides that a resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Section 483.10(j)(1) further specifies that such grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their long-term care facility stay. When considering these other approaches to defining what constitutes a grievance, we concluded that the definition used in PACE is already tailored more narrowly than the MA or nursing home requirements. That being the case, we do not believe it would be appropriate to narrow the definition even more, and potentially limit a PACE participant's ability to complain about their care and have their complaints resolved through a formal process.

However, we recognize that there are aspects of the MA regulations' definition of grievance that would be helpful to include in the PACE definition at § 460.120, because it would further refine the grievance definition and offer clarity sought by PACE organizations in previous feedback. For example, in developing our proposal, we noted that the MA regulations specify that a grievance is any complaint that meets the definition at § 422.561 regardless of whether remedial action is requested. We have seen on audit where PACE organizations will not recognize or process complaints that fit within the definition of a grievance, because remedial action was not requested. However, we want to stress that a grievance must be identified and processed if it satisfies the definition, regardless of whether remedial action is requested. This is an important participant safeguard because grievances are required under the current § 460.120(f) to be maintained, aggregated and analyzed as part of the PACE organization's quality improvement program. Regardless of whether remedial action is requested, it is important for organizations to analyze all complaints received in order to ensure they are making necessary improvements in their quality program. For these reasons, we propose to include in our definition of a grievance that a request for remedial action is not required.

In further consideration of MA grievance regulations, and specifically MA grievance procedures at § 422.564, we propose that the definition of a grievance would provide that a grievance may be between a participant and the PACE organization, but it may also be between any other entity or individual through which the PACE organization provides services to the participant. This proposed change to the PACE grievance definition is based on the MA grievance definition, which provides at the current § 422.564(a) that each MA organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers. PACE provides a wide array of services through different home care agencies, medical specialists, and facilities such as nursing homes. It is important that a participant or their family have the ability to voice complaints related to any care they receive, even if that care is provided through a contracted entity or individual.

We are proposing the grievance definition at § 460.120(b) be: ''For purposes of this part, a grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant.'' However, we would like to solicit comment on whether we should modify the PACE grievance definition to more closely resemble the definition of grievances in MA at § 422.561. Specifically, we solicit comment on whether we should consider use of the following definition for PACE grievances: A grievance means any complaint or dispute expressing dissatisfaction with any aspect of the PACE organization's or it's contractors'

operations, activities, or behavior, regardless of whether remedial action is requested.

Currently, § 460.120(b) requires that upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process. We are proposing to redesignate § 460.120(b) as § 460.120(c), change the title, and amend the regulation text. Specifically, we propose to change the title from notification to participants to grievance process notification to participants, to differentiate from notifications related to grievance resolutions, and that the grievance process notification be written in understandable language. We propose to add new paragraphs (c)(1), (c)(2), and (c)(3) to § 460.120, which would set forth requirements for the grievance process notification. We solicit comment on whether the other individuals should receive the grievance process notification, in addition to the participant, upon the participant's enrollment and annually thereafter. Specifically, we are soliciting comment on whether the other individuals specified in § 460.120(d) should receive the grievance process notification, or at a minimum, whether the participant's designated representative should receive the notification in addition to the participant.

First, we propose at § 460.120(c)(1) that the grievance process notification must include information on the right of the participant or other individual specified in § 460.120(d) to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal. In developing this proposal, we again considered the long-term care regulation at § 483.10(j)(1), and we believe that the language in the long-term care regulation that provides that a resident has the right to voice grievances without reprisal or discrimination and without the fear of reprisal or discrimination would also be relevant in PACE. PACE participants have the right to voice complaints to PACE staff without reprisal by the PACE staff under current § 460.112(g)(1), but we believe this right should be specifically called out in the PACE regulations, as written in the long-term care regulations, in the notification that goes to participants about the grievance process. By including it in the notification under proposed § 460.120(c), we would ensure that participants would be aware of this right to complain, and that they are assured in that notification that they and the other individuals specified in § 460.120(d) should not fear making complaints. When we have conducted interviews of PACE participants and their family members as part of our audit process, we have heard that some participants are afraid to voice grievances for fear that the PACE organization will take some punitive action against them. For example, some participants have expressed fears that the PACE organization will eliminate their center attendance, or discontinue other necessary services, if the participant complains about the care they receive. We believe it is important for the grievance process notification to participants to emphasize that a participant or other individual specified in § 460.120(d) has the right to voice grievances without the fear of reprisal or discrimination.

We propose at § 460.120(c)(2) that the grievance process notification must inform pariticipants that a Medicare participant as defined in § 460.6 or other individual specified in § 460.120(d) acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services, consistent with section 1154(a)(14) of the Act. Section 1154(a)(14) provides that the QIO ''shall conduct an appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under title XVIII) not meeting professionally recognized standards of health care, if the complaint is filed with the organization by an individual entitled to benefits for such services under such title (or a person acting on the individual's behalf).'' Title XVIII of the Act is the Medicare statute, so this provision is specific to Medicare beneficiaries and Medicare-covered benefits. Since most PACE participants are Medicare beneficiaries, they are also eligible to submit quality of care grievances to a QIO. This right has not been formally provided to PACE participants before, and we are proposing to require it now in order to ensure that Medicare beneficiaries enrolled in PACE understand this additional right.

We propose at § 460.120(c)(3) to require that the grievance process notification include the grievance definition at § 460.120(b) and provide information on all grievance processing requirements in paragraphs (d) through (k) of § 460.120. In order for the grievance process to serve as a fair and efficient avenue for participants to express their dissatisfaction with service delivery or the quality of care furnished, and to resolve their differences with the PACE organization or any other entity or individual through which the PACE organization provides services to the participant, participants must understand how to submit a grievance to the organization, and how that grievance will be processed once submitted.

Currently, at § 460.120(c), PACE organizations are required to develop written procedures that, at a minimum, must address how a participant files a grievance, documentation of the participant's grievance, response to and resolution of a grievance in a timely manner, and maintenance of confidentiality of a participant's grievance. These requirements allow PACE organizations to develop their own procedures for resolving grievances, including creating their own timeframes for doing so. Given the frail and vulnerable population in PACE, we believe that additional structure around how grievances should be processed is necessary. Therefore, we are proposing to remove the language that is currently at § 460.120(c) and create specific processing requirements in its place.

We propose to move the language regarding who can submit a grievance from current § 460.120(a) to a new paragraph at § 460.120(d), as we believe the details regarding who is eligible to file a grievance will be more easily understood if they are placed in a new paragraph and separated from the remainder of § 460.120(a), which, under our proposed amendments, would require PACE organizations to have a formal written process to promptly identify, document, investigate, and resolve all grievances. Current § 460.120(a) provides that grievances can be submitted by participants, family members or their representatives. We propose to amend the list of individuals who can submit a grievance to include the participant's caregiver. We believe the proposed addition would be in alignment with the service determination process requirements in § 460.121, which allow a participant's caregiver to request services (§ 460.121(c)(3)), and with the plan of care requirements at § 460.106, which allow the caregiver to be involved in the development and reevaluation of the care plan (§ 460.106(e)).

As we stated in the January 2021 final rule (86 FR 6018), given the fact that caregivers may provide some care to the participants, it is important that caregivers are able to advocate for services on the participant's behalf. Similarly, if caregivers are providing some care to the participant, they should be able to make complaints related to any aspect of the care that the participant receives from the PACE organization. Since the grievance

regulation already allows for family members and representatives to submit a grievance, we believe the change to add the term caregivers will not create a substantial change or burden for PACE organizations, since we believe that most caregivers will fall into one of the categories of family member or representative. As we explained in the January 2021 final (86 FR 6018), we have not historically considered ''caregivers'' to include employees or contractors of the organization. We know some organizations may use the term ''caregiver'' to describe an aide at a nursing home, but CMS would not generally consider these individuals to fall within this category. We also explained in that rule (86 FR 6018) that employees and contractors of the PACE organizations enter into a contractual relationship with the PACE organization and generally have a predominately financial incentive to provide care; and we have not considered these individuals to be ''caregivers'' under the regulations. While these paid individuals may have pertinent information related to the participant's care, their feedback is captured under the requirements for the IDT to remain alert to pertinent information under current § 460.102(d)(2)(ii). We do not believe that these paid individuals would generally be entitled to file a grievance under § 460.120. We solicit comment on our proposal to amend the list of individuals who can submit a grievance to include a participant's caregiver.

In order to provide more clarity regarding CMS' expectations for recognizing and processing complaints as grievances, we believe it is appropriate that we add additional structure to the regulations concerning how a grievance may be submitted, similar to how the service determination regulations are structured. We propose to add these rules around the submission of grievances in new paragraph § 460.120(e).

Proposed § 460.120(e)(1) would provide that any individual permitted to file a grievance with a PACE organization under § 460.120(d) may do so either orally or in writing. Currently, the introductory text of § 460.120 allows for a grievance to be filed orally or in writing. The right to file a grievance orally or in writing is an important participant safeguard, especially in an aging population, and it should continue to appear in our regulations. However, we believe it is more appropriate that we codify this right in a separate provision (as opposed to folding it into the definition of the term grievance, as in current § 460.120) in new proposed paragraph (e), along with the other proposed requirements for the submission of grievances. Proposed § 460.120(e)(2) would establish that the PACE organization may not require a written grievance to be submitted on a specific form. While we understand that some organizations may use forms to help them process and investigate the grievance, we do not believe that a PACE participant should be restricted in how they can submit the complaint. We have seen participants detail their complaints to PACE organizations in letters and email correspondence. Receipt of these written complaints should be considered grievances and accepted in their original form. If a PACE organization decides to create a grievance form on its own and summarize the original grievance, that would continue to be permitted under our proposal, as long as the PACE organization maintains the written communication in its original form as required by § 460.200(d)(2).

Proposed § 460.120(e)(3) would provide that a grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants. This language is similar to the method for filing a service determination request at § 460.121(d)(2). As we indicated in the January 2021 final rule (86 FR 6019), these are the settings where participants have the most frequent contact with employees or contractors of the PACE organization, and therefore are logical settings for service determination requests to occur. We believe the same logic can be applied to grievances, and as a result, we limited our proposal to employees and contractors working in these settings.

We propose at new § 460.120(f) to establish the requirement that the PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known. Investigating why the situation occurred is an important part of ensuring that appropriate action will be taken in response to a grievance. However, we also recognize there may be some situations where the cause for the complaint or a specific issue is already known and therefore an investigation is not needed. For example, if the PACE bus has a flat tire, and as a result is late to pick up a participant for their center attendance, the participant may complain to the PACE organization about the late pick-up. While this would constitute a grievance and would need to be identified and processed, an investigation would not be necessary because the PACE organization was already aware of the cause of the complaint (that is, the flat tire). If there are multiple issues within a grievance that require investigation, proposed § 460.120(f) would require the PACE organization to conduct a thorough investigation into each distinct issue when the cause of an issue is not known. We have seen on audit that some complaints may contain different issues within the one grievance. For example, a participant may call to complain that their home care aide is routinely late and does not clean the kitchen as is care planned for that participant. These are 2 different issues and both may need to be investigated in order to appropriately resolve the grievance. The PACE organization as a result of its investigation may determine that while the aide was late due to poor time management skills, the kitchen was not being cleaned because the home care company did not have the most recent care plan for the participant. The results of the investigation would directly impact how the PACE organization would resolve these concerns.

We propose at new § 460.120(g) to establish resolution and notification timeframes that would apply to grievances. Specifically, we propose at § 460.120(g)(1) that the PACE organization must take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance. Again, we considered both the MA grievance regulations and also the long-term care regulations. While the long-term care regulations do not define a timeframe for resolving grievances, the MA regulation at § 422.564(e)(1) requires that an MA organization must notify an enrollee who submits a grievance of the organization's decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the organization receives the oral or written grievance. We believe this is a fair timeframe, and based on our oversight efforts, we believe that a majority of organizations currently utilize a similar timeframe for resolving grievances. In our proposal for the PACE grievance regulation, we propose to adopt a modified version of the requirement in the MA regulations, which would specify that the 30-day timeframe is the maximum amount of time the PACE organization has to resolve the

grievance, as opposed to the maximum amount of time to notify the participant. Proposed § 460.120(g) would maintain the language regarding ensuring that this timeframe is a maximum length of time, and that organizations may need to resolve grievances more quickly if the participant's case requires. We propose at § 460.120(g)(2) that the PACE organization must notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with § 460.120(g)(1). We contemplated combining both the notification and resolution of a grievance into a single timeframe, but ultimately decided against that. We believe that the act of resolving a grievance, and the act of notifying the submitter about the resolution, are two separate actions. Additionally, as we will discuss in this section of this proposed rule in relation to proposed new § 460.120(i), we believe this exception strengthens our rationale for having distinct resolution and notification timeframes since we would expect a timely resolution of the grievance even if the individual who submitted the grievance requested not to be notified of that resolution.

Proposed § 460.120(h) would establish requirements for the processing of expedited grievances. Specifically, we propose to require that the PACE organization must resolve and notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 24 hours after the time the PACE organization receives the oral or written grievance if the nature of the grievance could have an imminent and significant impact on the health or safety of the participant. Because PACE organizations are direct care providers, it is important that they have a system for recognizing and processing complaints quickly when those complaints could have both an imminent and significant impact on the health or safety of the participant. We have not chosen to define the words ''imminent'' and ''significant'', because we believe PACE determine how they will define those terms as a part of their development of their grievance procedures. PACE organizations should already have some system in place to recognize similar situations as organization's are currently required as a part of their quality improvement program at § 460.136(a)(5) to immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant. It would be important for PACE organizations to have a procedures for quickly responding to those complaints that may have an imminent and significant impact on the participant's health or safety. For example, if a participant complains that a home care aide abused him or her, and the aide is due back in the home later that day, the PACE organization should be prepared to investigate and resolve that concern immediately.

We propose at new § 460.120(i) to create grievance resolution notification requirements for how the PACE organization must inform the individual who submitted the grievance of the resolution of that grievance. We propose at § 460.120(i)(1) that the PACE organization may inform the individual either orally or in writing, based on the individual's preference for notification, except for grievances identified in § 460.120(i)(3). We contemplated following the MA rule around notification in § 422.564(e)(3), which allows for oral grievances to be responded to orally or in writing, but requires written grievances to be responded to in writing. However, we understand that because PACE organizations are not only an insurer, but also a provider, they often have calls or other remote communications with participants, and likely talk with them more often than an MA organization would talk with one of their enrollees. We also understand that some PACE participants would prefer oral notification, even if they their grievance was submitted in writing. Likewise, some PACE participants may call with a grievance, but may want a formal written notice explaining the resolution. Therefore, we believe that PACE organizations should tailor the notification of the grievance resolution to what a PACE participant prefers.

We propose to establish at § 460.120(i)(2) that oral or written notification of grievance resolutions must include a minimum of three requirements. First, we propose at § 460.120(i)(2)(i) that the notification must include a summary statement of the participant's grievance including all distinct issues. This is especially important when a grievance cannot be resolved immediately and requires additional investigation. When notifying a participant or other individual who submitted the complaint, it would be important to restate the distinct issues of the grievance so they understand what the organization was investigating and resolving. Second, we propose at § 460.120(i)(2)(ii) that for each distinct issue that requires an investigation, the notification must include the steps taken to investigate the issue and a summary of the pertinent findings or conclusions regarding the concerns for each issue. As we stated earlier, we do not believe that every grievance, or every issue within a grievance, will require an investigation, and some issues may require minimal investigation; however, we believe that to the extent it is applicable it would be important for the individual who submitted the grievance to understand what the organization did during their investigation. Third, we propose at § 460.120(i)(2)(iii) that for a grievance that requires corrective action, the grievance resolution notification must include corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur. In the example we used earlier, we noted that during the investigation into the home care aide not cleaning the kitchen, the PACE organization discovered that the home care agency did not have the most current care plan for that participant. The correction that would likely result from that investigation would be to provide the updated care plan to the home care agency and ensure they have received and understand it. This action should be communicated to the participant in order for them to understand how their grievance has been handled and resolved.

Proposed § 460.120(i)(3) would set forth requirements related to how PACE organizations must provide notification when the complaint relates to a Medicare quality of care issue. Specifically, we propose that for Medicare participants, any grievance related to quality of care, regardless of how the grievance is filed, must be responded to in writing. This is consistent with the MA requirement in § 422.564(e)(3)(iii). As previously discussed, Medicare beneficiaries, and by extension, Medicare participants enrolled in PACE, have the right to submit quality of care grievances and complaints to a QIO under section 1154(a)(14) of the Act. We propose at § 460.120(i)(3) that, when a grievance relates to a Medicare quality of care issue, the PACE organization must provide a written grievance resolution notification that describes the right of a Medicare participant or other individual specified in § 460.120(d) acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. The only exception to this requirement to provide a written resolution notice

would be when the submitter specifically requests not to receive notification as specified in proposed § 460.120(i)(4), which is discussed in more detail in this section of this proposed rule. We also propose to specify that for any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint. This language is consistent with the language used in the MA program, and therefore we are proposing it be added to the PACE regulations as well. Because the QIO's statutory function related to review of quality of care concerns and responses to beneficiary complaints is only applicable to Medicare services and only available to Medicare beneficiaries, and because PACE organizations may have some participants who are not Medicare beneficiaries and may cover non-Medicare services, we expect PACE organizations to work with participants to help them understand whether their grievance relates to a Medicare quality of care issue.

We propose to establish at new § 460.120(i)(4) that the PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive notification of the grievance resolution, and the PACE organization has documented this request in writing. We have heard through our auditing experience that some participants may wish to remain anonymous and some may want to submit a complaint, but they may not wish to receive any notification of the resolution. In order to balance the need for an organization to track and process grievances, with respect for the preferences of participants who wish to not receive communications related to the resolution of a grievance after submitting the initial complaint, we propose to specify in new § 460.120(i)(4) that PACE participants must have an option to request not to receive any further communication or notification of the grievance resolution following their initial complaint submission. In order for a PACE organization to withhold notification of the grievance resolution for participants who request to exercise this option, the PACE organization would be required to document the participant's request in writing. We propose to include in new § 460.120(i)(4) language that provides that the PACE organization would still be responsible for all other parts of this section.

Section 460.120(d) specifies that the PACE organization must continue to furnish all required services to the participant during the grievance process. We propose to redesignate current § 460.120(d) as § 460.120(j) to account for our other proposals.

Currently, § 460.120(e) requires a PACE organization to discuss with and provide to the participant in writing the specific steps, including the timeframes for response, that will be taken to resolve the participant's grievance. We believe our proposals at § 460.120(c) and § 460.120(i) would ensure that PACE participants receive sufficient notification regarding both the general grievance process and how a specific grievance was resolved. Therefore, we propose to remove current § 460.120(e).

We propose to add a new paragraph § 460.120(k) that would redesignate and modify the requirement that is currently included at § 460.120(c)(4). Specifically, we are proposing that the PACE organization must develop and implement procedures to ensure that they maintain the confidentiality of a grievance, including protecting the identity of any individuals involved in the grievance from other employees and contractors when appropriate. As we stated when discussing the proposed notification requirements at § 460.120(i)(4), we understand that some grievances may be sensitive and some participants or other submitters may wish for their complaint to be kept confidential. For example, if a participant has a complaint related to their physical therapist, that participant may not want the physical therapist to be aware of the complaint. We expect that organizations consider these situations, and have a method for participants that may want certain information to be kept confidential. There may be instances where a person submitting the complaint may want their identity to be protected, or where the complaint involves a sensitive matter where the identity of all individuals may need to be protected, and we would expect the PACE organization to have a process for ensuring that there is a way to maintain the confidentiality of the identity of any individual involved in the grievance from other employees or contractors when it is appropriate. However, we would reiterate that accepting and processing a confidential grievance would not negate the PACE organization's responsibilities to investigating and resolving the grievance. It also would not negate the responsibilities to document, aggregate and analyze the grievance, as required under current § 460.120(f). Also, as we discussed earlier, we have heard from multiple PACE participants that sometimes participants or their family members are afraid to complain to the PACE organization for fear of reprisal. While we require a PACE organization to ensure that confidentiality of a grievance is maintained, we also want to remind PACE organizations that participants have the right to submit grievances without fear of reprisal. We have heard through oversight and monitoring activities that participants are afraid that they will lose necessary services, or not be approved for services, if they complain regarding the care received by an organization. PACE organizations should ensure that all participants understand that they are free to complain without any fear of reprisal, regardless of what their grievance is about.

We propose to add a new paragraph at § 460.120(l) that aligns with the record keeping requirements for service determination requests, which are set forth at § 460.121(m). Specifically, proposed § 460.120(l) would require that a PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. These records, except for information deemed confidential as a part of § 460.120(k), must be available to the IDT to ensure that all members remain alert to pertinent participant information. We expect that PACE organizations have appropriate mechanisms in place for documenting all complaints, including ensuring that oral complaints are documented appropriately, and that written complaints are maintained as required in § 460.200(d)(2). We believe that proposed § 460.120(k), similar to the § 460.121(m) service determination request, would ensure that all relevant parts of the grievance process are documented, including details of the investigation, the findings, any corrective action that was taken, and the notification (oral and/or written) that was provided to the participant of the resolution.

Finally, current § 460.120(f) requires PACE organizations to maintain, aggregate, and analyze information on grievance proceedings. This information must be used in the PACE organization's quality improvement program. We are proposing to redesignate this as paragraph (m) to account for our other proposals. We are also proposing to remove the word ''maintain'' that appears in the current regulation text, since the requirement to maintain records has been added to the proposed paragraph (l). Redesignated § 460.120(m), as revised under our proposal, would state that the PACE

organization must aggregate and analyze the information collected under paragraph (l) of this section for purposes of its internal quality improvement program. We note that this requirement applies to all grievances; oral or written, including anonymous grievances. We have seen through audit that some organizations do not include all grievances as a part of their internal quality improvement analysis. It is important that PACE organizations consider all complaints that constitute a grievance in order for them to make adequate improvements to their program.

We estimate a one-time burden for PACE organizations to update their grievance materials to meet these proposed requirements. We do not believe there will be a change in annual burden as a PACE organization is already required to provide notification to participants on their grievance resolution, and may opt to do so orally or in writing. Therefore, we believe that the ongoing burden will not change with this proposal. We discuss and account for the one-time burden for PACE organizations to update their grievance materials to meet the proposed new requirements in the Collection of Information Requirements section. We will submit these changes to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on December 31, 2023.

We solicit comments on this proposal.

L. Service Determination Request (§ 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 participant, including procedures for grievances and appeals. Along with the regulations at § 460.120 related to grievances, and § 460.122 related to appeals, CMS created a process for service determination requests, the first stage of an appeal, at § 460.121.

A service determination request is defined at § 460.121(b)(1) as a request to initiate a service, to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service, or to continue coverage of a service that the PACE organization is recommending be discontinued or reduced. Once a service determination request is received by the full IDT, the IDT must make a decision on the request and provide notification of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the IDT receives the request, except that the IDT may extend the timeframe for review and notification by up to 5 calendar days if the extension requirements as specified in § 460.121(i)(1) are met. When CMS proposed [223] to require service determination request extension notifications in § 460.121(i)(2), we based the requirement on the MA organization determination requirements in § 422.568, which require written notification when an extension is taken. Comments submitted by PACE organizations and industry advocacy groups regarding our proposal to require written notification of extensions recommended we allow either oral or written notification when the IDT extends the timeframe for a service determination request, rather than requiring written notification only. At the time, we did not finalize the change to allow oral or written notification for extension requests, and we explained that we believed written notification of the extension was important in order to ensure the participant received a full explanation. Additionally, we explained that providing written notification of the extension would allow the participant to share the information with family members or caregivers, if desired (86 FR 6022).

Since that rule was finalized, PACE organizations have had an opportunity to implement the provision and assess whether written notification is practical for all extensions. Additionally, since the rule was finalized, PACE organizations have been operating under a worldwide pandemic, which has required organizations to increase their ability to engage participants in new ways through the use of remote technology, and utilizing different means of communicating orally has become more prevalent and has proven an effective way to communicate important information quickly. For these reasons, we are now proposing to revise the requirement in § 460.121(i)(2) to allow the IDT to provide notification either orally or in writing to the participant or their designated representative when the IDT extends the timeframe for a service determination request, as permitted under § 460.121(i)(1). Allowing the IDT to provide either oral or written notice of service determination request extensions would increase operational flexibility for PACE organizations without compromising participant safeguards. In order to ensure participants are fully informed of the reason(s) for an extension, we expect oral notice of the service determination request extensions to meet the same requirements as written notice, including the expectations that notices will explain the reason(s) for the delay and be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe. We also expect that PACE organizations would document the content of oral notifications of service determination request extensions in accordance with § 460.121(m). An IDT may choose to provide the extension notification both orally and in writing if it believes that is necessary to ensure the participant's understanding.

We estimate ongoing burden reduction due to the expected decrease in written notifications of service determination request extensions in favor of oral notification. We discuss and account for the burden reduction resulting from the expected decrease in written notification of service determination request extensions in the Collection of Information Requirements section. We will submit these changes to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on December 31, 2023.

We solicit comment on this new alternative.

M. Participant Notification Requirement for PACE Organizations With Performance Issues or Compliance Deficiencies (§ 460.198)

Sections 1894(f)(3) and 1934(f)(3) of the Act provides CMS the discretion to apply such requirements of Part C of title XVIII and sections 1903(m) and 1932 of the Act relating to protection of beneficiaries and program integrity as would apply to Medicare Advantage (MA) organizations under Part C and to Medicaid managed care organizations under prepaid capitation agreements under section 1903(m) of the Act. Some examples of where CMS has previously exercised this discretion include the development and implementation of requirements related to PACE compliance and oversight, PACE enforcement actions (CMPs, sanctions, and termination), and PACE participant rights and protections.

Under §§ 422.111(g) and 423.128(f), CMS may require an MA organization or Part D plan sponsor to disclose to its enrollees or potential enrollees, the MA organization or Part D sponsor's performance and contract compliance deficiencies in a manner specified by CMS. The purpose of these beneficiary protections is to provide beneficiaries with the information they need to assess

[223] CMS included this proposal in the February 2020 proposed rule (85 FR 9002).

the quality of care they are receiving and to make sponsoring organizations accountable for their performance deficiencies, which should improve compliance with the rules and requirements of the Medicare program. Further, in the final rule titled ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (75 FR 19677), which appeared in the April 15, 2010 issue of the **Federal Register**, CMS explained that ''our intent is to invoke this disclosure authority when we become aware that a sponsoring organization has serious compliance or performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified. One example of a situation where enrollees should be notified of performance or compliance deficiencies would be when a sponsoring organization fails to provide beneficiaries with the proper premium notices to collect premium amounts in arrears. Another example would be if a sponsoring organization failed to provide access to services and we instructed the sponsor to contact enrollees regarding this issue and assist them with obtaining needed services or medications. In each of these situations we would require a sponsoring organization to disclose the deficiency to its enrollees and take affirmative steps to alleviate any problems for enrollees, such as providing enrollees with options to fix the issue'' (75 FR 19734–19735).

In contrast to the Part C and D regulations at Parts 422 and 423, respectively, the PACE regulations at Part 460 do not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies. In addition, we note that although regulations at Part 423 generally apply to PACE organizations, § 423.128 was waived for PACE organizations in 2005 (*see* January Part D 2005 final rule (70 FR 4430, 4432–4433)). However, we believe the disclosure of this information would serve as an important protection for PACE participants, as it would help to ensure current and potential PACE participants and their caregivers have adequate information to make informed decisions about whether to enroll in or to continue their enrollment with a PACE organization. PACE participants that are enrolled in the organization and their caregivers should have notice of the PACE organization's performance and compliance deficiencies in order to assess whether they have experienced similar issues that must be addressed by the PACE organization. In addition, for participants that are looking to enroll in a PACE organization, it is important they understand any potential issues that they may experience if they proceed with their enrollment. Finally, it is important to ensure there is public transparency regarding a PACE organization that has, or has had, performance and contract compliance deficiencies.

Therefore, effective beginning in CY 2024, we propose to amend the regulations at Part 460 by adding § 460.198, which would require PACE organizations to disclose to current PACE participants and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS. As in the MA and Part D programs, we anticipate that we would invoke the disclosure requirement when we become aware that a PACE organization has serious compliance or performance deficiencies such as those that may lead to intermediate sanctions or requires immediate correction, and where we believe PACE participants and potential PACE participants should be specifically notified.

Consistent with § 423.128(d), CMS waives any provision of the Part D regulations to the extent that CMS determines that the provision is duplicative of, or conflicts with, a provision otherwise applicable to PACE organizations under sections 1894 or 1934 of the Act, or as necessary to promote coordination between Part D and PACE. Because sections 1894 and 1934 of the Act do not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies, the regulation at § 423.128(f) does not duplicate, conflict with, or impede coordination between Part D and PACE. In addition, we note that, at the time CMS announced the waiver of § 423.128 in the January Part D 2005 final rule (*see* 70 FR 4432–4433), the disclosure requirement in paragraph (f) did not appear in § 423.128.[224] Therefore, we believe the 2005 waiver of the rest of § 423.128 does not apply to § 423.128(f), and the disclosure of information regarding performance and contract deficiencies concerning a PACE organization in its capacity as a Part D sponsor would serve as an important protection for PACE participants, as it would help to ensure current and potential PACE participants and their caregivers have adequate information to make informed decisions about whether to enroll in or to continue their enrollment with a PACE organization. This proposed rule does not impact the waiver of the remainder of § 423.128 for PACE organizations, as applicable.

[224] The April 2010 final rule (75 FR 19677) amended § 423.128 to include paragraph (f).

N. PACE Maintenance of Records (§§ 460.200 and 460.210)

Under sections 1894(b) and 1934(b) of the Act, PACE organizations are required to provide all items and services covered under Medicare and Medicaid, and all additional items and services specified in regulations and determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status. Currently, PACE organizations are required to safeguard data and records in accordance with § 460.200(d). PACE organizations must also maintain a single comprehensive medical record for each participant in accordance with accepted professional standards (§ 460.210(a)(1)).

In the February 2020 proposed rule (85 FR 9002), CMS proposed to add a new requirement at § 460.200(d)(2) for PACE organizations to maintain in the medical record 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). We explained in the proposed rule that we had found through our monitoring of PACE organizations that they 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 (85 FR 9134). We stated 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 and safety, and to provide appropriate and timely care to the participant (85 FR 9140). Therefore, we also proposed a new requirement at § 460.210(b)(6) for PACE organizations to maintain in a participant's medical record 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 (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; and (ii) communications from an advocacy or governmental agency such as State-based Adult Protective Services.

In the January 2021 final rule, CMS summarized and responded to the comments received on these proposed record maintenance requirements (86 FR 6039 through 6040). We noted that some commenters recommended we allow PACE organizations to maintain original communications *outside* of the medical record systems, as they believed that maintaining original documentation of any written communication relating to the care, health or safety of a participant in any format *in* the medical record would compromise the usefulness of the medical record, due to the quantity of information that would be required to be stored (86 FR 6040). Based on these comments, we contemplated allowing original documentation of communications to be summarized in the medical record, so long as PACE organizations maintained the original documentation of the communication in a separate system. Ultimately, we chose not to modify our proposal with the contemplated change of permitting PACE organizations to summarize written communications relating to the care, health, or safety of a participant in the medical record. We did, however, modify our original proposal to allow PACE organizations to maintain in a participant's medical record original documentation, or an electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant. In finalizing this provision, we explained that we were not establishing specific requirements governing where affected communications must be stored within a participant's medical record. We also explained that PACE organizations may operationalize these requirements in accordance with the capabilities of their medical record systems (86 FR 6040).

Participants, their family members, and representatives have a longstanding right to file a grievance expressing dissatisfaction with the delivery of PACE services or the quality of care furnished as part of the PACE benefit package (see §§ 460.112(g)(1) and 460.120). A PACE organization must have a formal written process to evaluate and resolve medical and non-medical grievances by PACE participants (§ 460.120(a)). A PACE organization's grievance process must include a written procedure for maintaining the confidentiality of a participant's grievance (§ 460.120(c)(4)).

PACE participants routinely file grievances with a PACE organization under the assumption that the details of their grievance will be kept confidential. This is especially important to PACE participants when a grievance involves a particular staff member of the PACE organization (for example, a home care aide, a driver, or a specific member of the interdisciplinary team). PACE organizations have typically maintained confidentiality of this information by only allowing access to the information, that is, the details of the complaint, to a limited number of PACE organization staff and/or by storing this information outside of the medical record in a secure location (for example, a separate electronic application or paper-based system).

Since we finalized the January 2021 final rule, PACE organizations have had an opportunity to implement this provision, and we have continued to receive questions related to maintaining original communications in the medical record. These questions and comments indicate that as PACE organizations have begun to operationalize this requirement, they have been challenged with maintaining the confidentiality of grievances and managing the volume of these communications in the medical record. Other inquires include whether it would be permissible for PACE organizations to scan communications and store them electronically in the medical record.

In addition to the concerns around maintaining the confidentiality of grievances, PACE organizations have also pointed out that there are instances when written communications sent to the PACE organization by the individuals and entities listed at § 460.210(b)(6)(i) and (ii) may contain sensitive information about a PACE participant, their caregivers, and/or family members, and that these communications are often accompanied by a request to keep the information private. For example, information shared with a PACE organization may pertain to a caregiver's health, and may have implications for the participant's care, and the caregiver may only want the details of this information shared among employees and contractors who need to know the information rather than all individuals with access to the participant's medical record. There are also instances when the communications include contents or language that may be inappropriate for inclusion in the medical record, such as vulgar comments directed towards individual PACE staff. PACE organization staff have indicated that maintaining written communications related to participant grievances in the medical record allows access to the information by all PACE organization staff, thereby jeopardizing the confidentiality of such communications, and have therefore requested clarification from CMS on how to adhere to comply with the requirement in § 460.210(b)(6) when the original communication is part of a participant grievance and contains sensitive or confidential information.

Sections 1894(f)(3) and 1934(f)(3) of the Act provide authority for the establishment of certain additional beneficiary and program protections applicable to MA and Medicaid managed care programs under prepaid capitation agreements under section 1903(m) of the Act. Sections 1894(b)(2) and 1934(b)(2) of the Act require that the PACE program agreement have written safeguards of the rights of enrolled participants, including a bill of rights and procedures for grievances and appeals, in accordance with regulations and with other Federal and State laws designed for the protection of beneficiaries. This authority allows CMS to implement regulations to ensure that PACE participants' rights are protected, including the right to file a grievance anonymously.

To uphold participant rights and help PACE organizations to safeguard anonymity to the extent possible during the grievance process and in other circumstances that involve sensitive information, CMS now proposes, using the authority at sections 1894(f)(3) and 1934(f)(3) of the Act, to amend the PACE regulations at §§ 460.200(d)(2) and 460.210(b)(6) to allow for more administrative flexibility in how PACE organizations maintain written communications relating to the care, health, or safety of a participant.

Specifically, we propose to amend § 460.200(d)(2) to require that a PACE organization must maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant's care, health, or safety, 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 care, health or safety; and (ii) communications from an advocacy or governmental agency, such as Adult Protective Services. This proposal would move and revise language currently located in

§ 460.210(b)(6) that requires PACE organizations to maintain original documentation, or an unaltered electronic copy, of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format. By moving this language to § 460.200(d)(2), with the proposed modifications, we would retain the requirement for PACE organizations to maintain these important communications in their original form, while removing the requirement that these communications be stored in the participant's medical record. At § 460.210(b)(6), we propose to replace the current language with a new requirement that states that original documentation or an unaltered electronic copy, of any written communication as described in § 460.200(d)(2), must be maintained in the participant's medical record unless the following requirements are met: (i) the medical record contains a thorough and accurate summary of the communication including all relevant aspects of the communication, (ii) original documentation of the communication is maintained outside of the medical record and is accessible by employees and contractors of the PACE organization when necessary, and in accordance with § 460.200(e), and (iii) original documentation of the communication is available to CMS and the SAA upon request. This proposal would continue to require PACE organizations to ensure that these important communications relating to the care, health, or safety of a participant are included in the medical record, but it would allow PACE organizations operational flexibility on how these communications are included. PACE organizations would be permitted, under this proposal, to summarize the information in the medical record, as long as the summary is accurate and thorough, and the original documentation of the communication is maintained outside the medical record and is accessible by the PACE organization's employees and contractors as needed, and available to CMS and the SAA upon request. We believe this proposal would balance CMS' interest in ensuring these communications are safeguarded with PACE organizations' interest in ensuring the medical record is usable and that confidential information may be protected to the extent possible. A PACE organization would be able to include a summary of the information but could choose to exclude names or other potentially sensitive information, provided the requirements under proposed § 460.210(b)(6)(i) through (iii) have been met.

O. PACE Participant Health Outcomes Data (§ 460.202)

Sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act require PACE organizations to collect, maintain, and report data necessary to monitor the operation, cost, and effectiveness of the PACE program to CMS and the State administering agency (SAA).

Following publication of the 1999 PACE interim final rule, CMS established a set of participant health outcomes data that PACE organizations were required to report to CMS. In subsequent years, we have modified the participant health outcomes data on a routine basis to ensure that we are collecting data that is relevant and useful to our efforts to monitor and oversee the PACE program. According to 5 CFR 1320.15, at least once every 3 years, in order to comply with the Paperwork Reduction Act of 1995 (Public Law 104–13) (PRA), CMS is required to publish the proposed data collection and solicit public comment. The data collection requirements related to participant health outcomes data can be found in the information collection request currently approved under OMB control number 0938–1264 (CMS–10525). Section 460.202 currently requires participant health outcomes data reported to CMS and the SAA to be specified in the PACE program agreement; however, CMS does not routinely update program agreements based on changes to the required participant health outcomes data. As a result, the quality data collection specified in the program agreement is often out of date and no longer applicable within a few years.

Since the participant health outcomes data that PACE organizations must report to CMS and the SAA are specified and routinely updated through the PRA process which requires CMS to publish and solicit comments on these data, we propose to amend paragraph (b) of § 460.202 by striking the final sentence, which states, ''The items collected are specified in the PACE program agreement.'' This change would eliminate confusion regarding where the data collection requirements may be found. The PACE program agreement would still include a statement of the data collected, as required by § 460.32(a)(11), but it would not include the level of specificity regarding the data collection that is included in the CMS PRA information collection request approved under OMB control number 0938–1264. We believe that by modifying § 460.202 as proposed we would not be increasing the burden on PACE organizations as they are currently required to furnish information to CMS and the SAA through the aforementioned information collection request.

VII. 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 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. We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

A. Wage Data

To derive mean costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*), which, at the time of publication of this rule, provides May 2021 wages. In this regard, Table 7 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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TABLE 7: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Final Hourly Wage ($/hr)
All Occupations (Enrollees)	00-0000	28.01	0	28.01
Business operations specialists (all others)	13-1199	38.1	38.1	76.20
Compliance officers	13-1041	36.45	36.45	72.90
Computer programmer	15-1251	46.46	46.46	92.92
Computer systems analyst	15-1211	49.14	49.14	98.28
Dietician	29-1031	31.55	31.55	63.10
Family Medicine Physicians	29-1215	113.43	113.43	226.86
General Internal Medicine	29-1216	116.44	116.44	232.88
General operations manager	11-1021	55.41	55.41	110.82
Healthcare Social workers	21-1022	29.96	29.96	59.92
Healthcare technical workers, all other	29-9099	31.19	31.19	62.38
Lawyer	23-1011	71.17	71.17	142.34
Management analysis	13-1111	48.33	48.33	96.66
Medical and health services manager (PACE Center Manager)	11-9111	57.61	57.61	115.22
Occupational therapist	29-1122	43.02	43.02	86.04
Office and administrative assistant	43-9199	20.47	20.47	40.94
Passenger vehicle driver	53-3099	17.51	17.51	35.02
Personal care aides	31-1120	14.07	14.07	28.14
Pharmacist	29-1051	60.43	60.43	120.86
Physical therapist	29-1123	44.67	44.67	89.34
Physician all others	29-1229	111.3	111.3	222.60
Recreational therapist	29-1125	25.91	25.91	51.82
Registered Nurse	29-1141	39.78	39.78	79.56
Software developer	15-1252	58.17	58.17	116.34

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As indicated, except for enrollees (All Occupations), 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. However, the mean wage for enrollees (under All Occupations) applies to a group of respondents that varies widely from working and nonworking individuals and by respondent age, location, years of employment, educational attainment, and other factors. We are not adjusting this figure

for fringe benefits and overhead since this group includes many individuals who are not working.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II. through VI.) of this proposed rule.

1. ICRs Regarding Applying D–SNP Look-Alike Requirements To Plan Benefit Package Segments (§ 422.514)

We propose adding a new paragraph at § 422.514(g) to clarify that the D–SNP look-alike contracting limitations at § 422.514(d) through (f) apply to segments of the MA plan. This new paragraph will address instances we have seen since adopting § 422.514(d) through (f) where a specific segment of an MA plan looks like a D–SNP look-alike and would be subject to the contracting prohibitions in § 422.514(d) if the segment were treated as an MA plan. We believe that by applying the D–SNP look-alike contracting limitations only at the MA plan level without applying it to segments of plans, our existing regulation has an unintended and unforeseen loophole through which D–SNP look-alikes could persist, contrary to the stated objectives in our prior rulemaking.

Based on January 2022 Monthly Membership Report data, we estimate that the proposed change would result in three MA plan segments being identified as D–SNP look-alikes, and these D–SNP look-alikes would likely transition the approximately 3,000 current enrollees into another MA–PD plan offered by the same MA organization (or by another MA organization with the same parent organization as the MA organization) using the transition process described in § 422.514(e). Based on our analysis of proposed D–SNP look-alike transitions for contract year 2023, two D–SNP look-alikes in contract year 2022 are proposing to transition a combined total of approximately 7,000 D–SNP look-alike enrollees into two new non-SNP MA plan segments, which could create two new D–SNP look-alikes for contract year 2023.

In the June 2020 final rule (85 FR 33877 through 33880), we estimated each D–SNP look-alike would take a one-time effort of 2 hours for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. We also stated that, after the prohibition on D–SNP look-alikes was implemented, 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. These estimates were submitted to OMB for approval under control numbers 0938–0753 (CMS–R–267). In association with our June 2020 final rule, the requirement and burden estimates (5 respondents, 5 total responses, and 10 total hours) were approved by OMB under control number 0938–0753 (CMS–R–267).

Our proposed clarification at § 422.514(g) does not change the transition process nor our burden estimates. Additionally, the proposed addition of non-SNP MA plan segments to the contracting limitations at § 422.514 does not change our estimates that at most five plans (including PBP segments) per year would be identified as D–SNP look-alikes; therefore, the estimated number of respondents and burden estimates in control numbers 0938–0753 (CMS–R–267) would not change.

2. ICRs Regarding Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the LI NET Program (§ 423.2500 Through § 423.2536)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10831). At this time, the control number has yet to be determined, but will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

As described in section II.D.2 of this proposed rule, we expect that some beneficiaries will enroll in LI NET using methods that may entail providing information. Some beneficiaries, called ''immediate need beneficiaries'' may enroll in LI NET at the point-of-sale (POS) at a pharmacy because they are likely eligible for the Part D low-income subsidy (LIS), have immediate need for their prescription, and do not have Part D coverage. Some beneficiaries submit receipts for reimbursement for claims paid out of pocket; if they are eligible for LI NET they will be retroactively enrolled into the LI NET program by the LI NET sponsor. Another way for beneficiaries to potentially enrollment into LI NET is by complete an LI NET application form.

To estimate the total burden, we consider the burden for enrollees, pharmacists, and Part D sponsors separately. Each consideration entails counting the number of documents arising from point of sale enrollments, direct reimbursement forms, and LI NET application forms.

For Beneficiaries: To estimate the information collection burden for beneficiaries, we have estimated the number of beneficiaries submitting information to LI NET and time related to handling the information. We have not included burden estimates for individuals who would not be providing documentation, such as those CMS automatically enrolls into LI NET, individuals whose eligibility for LI NET is confirmed independently by the LI NET sponsor, or for those who opt not to provide evidence.

When enrolling in LI NET at POS, possible forms of evidence for LIS eligibility include but are not limited to, a Medicaid card, an LIS award letter, or a declaration to the pharmacist of LIS applicant status. We estimate that it would take an individual approximately 15 minutes (0.25 hr) to gather supporting documentation. There are 36,722 individuals enrolled in the LI NET demonstration at POS in 2021 who will apply at the point of sale. Based on our experience with the LI NET demonstration, we estimate approximately 250 beneficiaries would submit receipts for reimbursement for claims paid out of pocket. These beneficiaries may complete a direct reimbursement request form available online, and return by mail, email, or fax, together with their receipt, to the LI NET sponsor. In the LI NET demonstration, approximately ten beneficiaries per year complete the LI NET application form, which is available online, and return it to the LI NET sponsor by mail, email, or fax. Thus, in total we expect 36,982 beneficiaries (36,722 at point of sale plus 250 through direct reimbursement plus 10 applying via the LI NET application form) to spend 15 minutes (0.25 hr) resulting in an aggregate burden of 9,246 hours (36,982 enrollees * 0.25 hr) at an aggregate cost of $258,980 (9,246 hr. * $28.01/hr).

For the Private Sector (Pharmacists): We estimate that it will take 2 minutes (0.0333 hr) for a pharmacy to fax the documentation to the LI NET sponsor. However, pharmacists will not process the forms of enrollees who use direct reimbursement or the LI NET application form. Thus, pharmacists will only process the 36,722 enrollees at point of sale. Thus, the aggregate burden for pharmacists is 1,223 hours (36,722 enrollees * 0.0333 hr) at an aggregate cost of $147,812 (1,223 hr * $120.86).

For Part D Sponsors: The Part D sponsors will process the documents

received from all 36,982 enrollees. Part D sponsors are estimated to spend about 2 minutes (0.0333 hr.) to fax information and to CMS and process information. Thus, the aggregate burden for Part D sponsors is 1,232 hours (36,982 enrollees * 0.0333 hr) at an aggregate cost of $93,878 (1,232 hr * $76.20/hr).

3. ICRs Regarding Adding New Behavioral Health Specialty Types Subject to Network Adequacy Evaluation (§ 422.116)

In order to ensure that MA enrollees have access to provider networks sufficient to provide covered services, including behavioral health service providers, we are proposing to add new specialty types that will be subject to network adequacy evaluation under § 422.116. We are proposing to add Clinical Psychology, Clinical Social Work and Prescribers of Medication for Opioid Use Disorder under § 422.116(b)(1).

To determine the potential burden regarding this proposal, we considered cost estimates for CMS making programming updates to the HPMS system, which is utilized to conduct automated reviews; additional burden, including updating policies and procedures, for CMS contractor; and additional burden, including updating policies and procedures, for MA organizations.

We have determined that there is a $0 cost for programming HPMS with regard to this proposal. Adding new specialty types to the automated review conducted by HPMS would be covered under funding currently in place for updating the system.

The CMS contractor does not indicate any additional costs to carry out the work required by this proposal, therefore there is no impact.

We have determined that there is a $0 cost for MA organizations in regards to reporting new specialty types to CMS for their network adequacy reviews as this proposal requires. However, we have determined that there is a minimal one-time cost for MA organizations to update their policies and procedures associated with this proposal.

First, regarding reporting the proposed new specialty types to CMS, MA organizations are already conducting ongoing work related to network adequacy reviews that happen during the initial or service area application, or every three years for the triennial review. Further, organizations should already have these specialty provider types within network, as these are services covered by Medicare Part A and B and which are furnished by these specialty types, so there is no burden related to contracting with new provider types. This proposal would only require that the proposed specialty types be added to the Health Services Delivery (HSD) tables during any network adequacy evaluation requested by CMS. The time to conduct tasks related to adding additional specialty types on the HSD tables is negligible.

We understand that MA organizations will need to update their policies and procedures related to submission of HSD tables to ensure that the new required behavioral health specialty types are included. We estimate that a business operations specialist working at an hourly wage of $76.20/hr will take five minutes (0.0833 hr) for a one-time update of policies and procedures related to this task, at a cost of $6.35 (0.0833 hr * $76.20/hr). The aggregate burden is 62 hours (742 MA contracts * 0.0833) at a cost $4,724 (62 hours * 76.20/hr).

These changes will be submitted to OMB for approval under control number OMB 0938–1346. Subject to renewal, the control number is currently set to expire on November 30, 2024. It was last approved on January 13, 2022 and remains active.

4. ICRs Regarding Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

As described in section III.D. of this proposed rule, we are proposing to revise: (1) § 422.111(e) by establishing specific enrollee notification requirements for no-cause and for-cause provider contract terminations and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur; and (2) § 422.2267(e)(12) to specify the requirements for the content of the notification to enrollees about a provider contract termination.

This proposal to amend §§ 422.111(e) and 422.2267(e)(12) would impact MA organizations in terms of the burden required to identify those enrollees who must be notified of provider contract terminations per CMS requirements, to develop and send the required written notices, to develop the scripts for the required telephonic notices, and to make the required enrollee telephone calls and any necessary follow-up calls. However, CMS does not currently collect data regarding the widely variable number of provider contract terminations an MA organization undergoes in a given contract year, nor the number of enrollees affected by each termination. Therefore, we do not have information to estimate the extent of MA provider contract terminations, how many enrollees are affected and need to be notified per § 422.111(e), or how the MA program would be impacted as we see the effects of the proposed regulation.

The actual direct burden of this provision arises from MA organization staff hours spent, resources purchased, and enrollee notifications provided. MA organizations may also differ in how their spending for the proposed requirements evolves over time as they test strategies and redevelop their approaches to complying with the regulation.

Despite our inability to quantify certain burden for this proposal, we are able to estimate the one-time burden on MA organizations to update their existing written provider termination notice in compliance with the new required notice content that we are proposing at § 422.2267(e)(12)(ii). We expect MA organizations to engage in some routine software development to update their notice template and related systems to incorporate the new proposed requirements, which we are proposing will be delineated in a provider termination model document developed by CMS staff (thus not incurring COI burden). This proposed model will be posted for public review and comment in conjunction with the proposed rule's CMS–R–267 PRA package. We estimate that one or two software developers working at a wage of $92.92/hr will spend a total of 8 hours updating an MA organization's existing provider termination notice template and related systems based on CMS's model. With approximately 697 MA organizations impacted by this proposed change, this results in a total of 5,576 hours (697 MA organizations * 8 hours), at an aggregate cost across all MA organizations of $518,122 (5,576 hours * $92.92/hr). We are unable to estimate the burden for the proposed telephonic notice requirement at proposed §§ 422.111(e)(1)(i) and 422.2267(e)(12)(iii) because the number of primary care and behavioral health provider contract terminations an MA organization undergoes in a given contract year is unknown, as are the number of affected enrollees per termination.

5. ICRs Regarding Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization (§ 422.101)

The requirements and burden related to Clarifications of Coverage Criteria for

Basic Benefits and Use of Prior Authorization will be submitted to OMB for approval under control number (0938–0753) (CMS–R–267). As explained in section III.E. of this rule, we propose that MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations when making medical necessity determinations. This rule proposes that MA plans must follow Traditional Medicare coverage criteria as specified in NCDs, LCD, or Medicare laws (that is, in Medicare statutes and regulations).

This rule further proposes that in the absence of coverage criteria in an applicable Medicare statute or regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature and that this evidence must be made publicly available.

This rule also proposes a new requirement that in creating these internal policies, MA organizations must provide a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. We expect that each plan annually will have new policies that they create.

We believe that the public posting of the summary of evidence used to develop a plan's internal coverage criteria would require minimal time. We estimate that over the course of a year 2 business days or 16 hours would be an adequate estimate of time needed for a business operations specialist to make all postings. Thus the per contract burden is 16 hours at a cost of $1,219 (16 * $76.20) and the aggregate burden over 697 contracts is 11,152 hours (697 contracts * 16 hours/contract) at a cost of $849,782 (11,152 hr * $76.20/hr)

We invite stakeholder comment on all aspects of this proposal. More specifically, we ask (1) is our assumption that plans are already complying with the requirement of creating new guidance correct? (2) is our assumption of 16 hours annually sufficient? (3) Are there any other aspects of this proposal or its estimates upon which stakeholders have comments?

6. ICRs Regarding Utilization Management Committee (§ 422.137)

This rule proposes protections to help ensure that beneficiaries maintain access to medically necessary Part A and B services and drugs, while permitting MA plans to use utilization management tools, such as prior authorization. This proposed rule requires that MA plans establish and use a committee (similar to a P&T committee) that reviews PA policies annually to ensure the policies are consistent with current traditional Medicare coverage and guidelines in Medicare statutes and regulations, NCDs, and LCDs. This proposed rule requires the committee to review all medical services that require PA and other utilization management policies, at least on an annual basis and to document their findings. Additionally, the committee would be responsible for revising and updating the MA plan's utilization management policies as needed.

Specifically, we propose at 422.137 (c)(1) through (4) that the UM committee must clearly articulate and document processes to determine that the committee membership requirements under the proposed 422.137 (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. We estimate it would take 1 hour at $76.20/hr for an UM Committee business specialist to perform certain tasks and review and retain documentation and information on an annual basis. Additionally, we propose at § 422.137(d)(4) and (5) that the committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. We estimate that it will take 2 hours at $ 76.20/hr for a UM Committee business specialist to capture and retain this required documentation on an annual basis. We invite stakeholder comment on these assumptions.

The aggregate burden for each of the 697 MA plans would be 2,091 hours (697 plans * 3 hours) at a cost of $159,334.2 (2,091 hours * 76.20/hr).

7. ICRs Regarding Review of Medical Necessity Decisions by a Physician or Other Health Care Professional With Expertise in the Field of Medicine Appropriate to the Requested Service (§§ 422.566 and 422.629)

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

In section III.N. of this proposed rule, we have proposed to strengthen the current requirement at §§ 422.566(d) and 422.629(k)(3) for who must review an organization determination or an integrated organization determination when the MA organization or AIP expects to issue a partially or fully adverse medical necessity decision.

Under the existing requirements, if a plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. We are proposing that additionally, the reviewing physician or health care professional must have expertise in the field appropriate to the requested service. As discussed in the preamble, this proposal will also apply to coverage denials from section 1876 cost plans and healthcare prepayment plans because §§ 417.600 and 417.840 require those plans to comply with the requirements in the MA regulations regarding organization determinations.

We next discuss the implications of this proposal for staffing and for appeals. We do not believe this proposal will impose additional staffing burden on plans. In light of existing review requirements applicable to organization determinations and integrated organization determinations, coupled with the requirements at § 422.152 for MA plans (including AIPs) to engage in ongoing quality improvement (including in processing requests for initial or continued authorization of services) and the contract requirement provisions at § 422.504, we believe plans already have the requisite expertise in staffing to satisfy the proposed requirement. Therefore, the proposed requirement that the physician or other appropriate health care professional have expertise in the field appropriate to the requested service may at most result in plans reallocating staff resources in certain

cases to ensure that someone with appropriate expertise is reviewing the request; however, we don't believe that this proposal will require additional staffing for MA organizations and AIPs.

If this proposal is finalized, MA organizations and AIPs would maintain the flexibility to utilize a physician or other health care professional, so long as they have expertise in the field of medicine that is appropriate for the services at issue. Under this proposed approach, an appropriate physician or other health care professional with expertise appropriate to the requested service would be reviewing the coverage request at a lower level of review.

However, this proposed provision would enhance medical review activities and plan operations related to organization determinations resulting in reduced burden. We note that the existing medical necessity review function is not identified as a separate line item in the aforementioned PRA package (CMS–R–267). However, this function is inherent in, and bundled into, the overall processing of organization determinations and appeals that is accounted for in this package. Because a separate and discrete burden estimate has not previously been submitted to OMB for the medical necessity review function, we are requesting OMB's review and approval under the aforementioned control number. The following table summarizes relevant plan reported data we have on organization determinations and our estimates related to this proposal to require medical review by physicians or other health care professionals with expertise in the field of medicine appropriate to the requested service. As explained more fully below, if this proposal is finalized we expect savings due to fewer denied organization determinations getting into the appeals process as a result of enhanced medical necessity review by appropriate experts.

TABLE 8: EXPECTED IMPACT OF PROPOSAL ON APPEALS

Item	Current Regulations	Proposed Under CMS-4201-P	Comments
Number of pre-service decisions	31,346,194	31,346,194	No change
Percent of unfavorable pre-service organization determinations	0.057	0.0285	We assume a savings of 50% in unfavorable decisions
Number of unfavorable pre-service organization determinations	1,786,733	893,367	Product of previous two rows (-893,366 or roughly 50% savings)
Percent of unfavorable pre-service organization determinations that are appealed	0.09	0.09	No change
Number of unfavorable pre-service organization determinations that are appealed	160,806	80,403	Product of previous two rows (-80,403 or 50% savings)
Percent of appeals resulting in an overturn	0.81	0.81	No change
Number of appeals resulting in an overturn	130,253	65,126	Product of previous two rows (-65,127 or roughly 50% savings)
Time for a single appeal notifications (hr)	0.25	0.25	No change
Total time (hr)	32,563	16,282	Product of previous two rows (-16,281 or roughly 50% savings)
Wage of business operations specialist	$76.20/hr	$76.20/hr	No change
Total Cost	$2,481,301	$1,240,688	Product of previous two rows

According to 2020 MA plan reported data, 1,786,733 (5.7 percent of all 31,346,194 Medicare pre-service organization determination decisions) are unfavorable coverage decisions (the decision is fully or partially unfavorable to the enrollee). Of this universe of unfavorable pre-service organization determinations, 160,806 cases (9 percent * 1,786,733) are appealed and subject to reconsideration by the plan. Of the cases reviewed on appeal, 130,253 cases (81 percent * 160,806 cases) of the reconsiderations resulted in a plan overturning its unfavorable organization determination.

Thus, the total burden is 32,563 hr (130,253 cases * 0.25 hr/case) at a cost of $2,481,317 (32,563 hr * $76.20/hr for a business operations specialist).

Assumptions about the proposal: There is a high percentage of cases overturned on appeal by the plan. We believe that strengthening the regulations at §§ 422.566(d) and 422.629(k)(3) to require the physician or other health care professional who reviews the initial coverage decision to have expertise in the field of medicine that is appropriate for the requested service or item ensure the appropriate level of protection for enrollees. For example, if plans are able to approve more coverage requests that involve medical necessity decisions at the organization determination level of review, this is likely to reduce costs associated with the administrative appeal process because fewer denials will occur at the initial level of review and, in turn, fewer cases are likely to get into the appeals process.

While we don't know with certainty what the reduction in existing denied organization determinations will be if this proposal is finalized, we believe it is reasonable to estimate that one-half (50 percent) of the existing volume of denials will result in a favorable decision given the enhanced standard of review. In other words, having a physician or other health care professional with expertise in the field of medicine appropriate to the requested service will result in a favorable organization determination decision, thereby reducing the number of cases potentially subject to appeal. In the absence of further information, we believe this a reasonable assumption. We solicit stakeholder input on the reasonableness of this assumption and whether their experience suggests some other savings.

Proposed Burden: Therefore, if this proposal is implemented, we estimate that 2.85 percent (one-half of the current rate of 5.7 percent), or 893,367 (0.0285 * 31,346,194 pre-service organization determinations) of the organization determinations will be unfavorable. At the previously stated appeal rate of 9 percent of unfavorable pre-service organization determinations being appealed to the plan, the number of cases will be 80,403 (0.09 * 893,367) reconsiderations (plan level appeals). Assuming the overturn rate of 81 percent remains, we expect overturns of 65,126 cases (0.81 * 80,403 cases).

We estimate that a physician spends 30 minutes reviewing a case for medical necessity. Under our proposal the same 30 minutes will be used for review; however, the review will occur at the organization determination level of review rather than at the appeal level of review. Thus, we expect no savings from physician review.

However, savings will occur as a result of a reduction is issuing appeal notices if the plan is able to approve more requests at a lower level of review (resulting in fewer appeals). We estimate that a business operations specialist spends 15 minutes generating and sending the notice of the appeal decision, or 16,282 hours (80,403 cases × 0.25hr/case) at a cost of $1,240,688 (16,282 hr * $76.20/hr).

Savings: To estimate savings associated with this proposed rulemaking, we note that the proposed rule estimates 50 percent of the burden of the current practice and hence the savings is also 50 percent. That is, the numbers in the column with proposed burden are numerically equal to the savings: 16,282 hours and $1,240,688 ($76.20/hr × 16,282).

We recognize that there are circumstances in which the plan is unable to make a fully favorable organization determination based on the information they have available to them before the end of the applicable adjudication timeframe. However, we believe that there remains a proportion of cases that contain the necessary information needed to approve coverage that may have a higher likelihood of approval if the individual reviewing the case has specific expertise related to the item or service being requested.

8. ICRs Regarding Strengthening Updating Translation Requirements Standards for Required Materials and Content: Require FIDE SNPs and HIDE SNPs and Applicable Integrated Plans to Translate Materials Into the Medicare Translation Standard Plus Additional Medicaid Languages (§§ 422.2267 and 423.2267)

We are proposing to require that FIDE SNPs, HIDE SNPs, and AIPs translate materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

This rule proposes to slightly modify existing policy, so the impact to FIDE SNPs, HIDE SNPs, and AIPs depends upon whether, and to what extent, these plans are already translating materials in ways that would meet our proposed requirements. We note that translation requirements vary by State. Therefore, we expect no impact in States where the applicable Medicaid and Medicaid translation requirements result in the same outcome. We expect marginal impacts where State requirements result in translation into languages not required by the current MA rules at §§ 422.2267(a)(2) and 423.2267(a)(2). However, even in these States, FIDE SNPs, HIDE SNPs, and AIPs (in combination with their affiliated Medicaid managed care plans) have translators on staff or access them via contractors because of existing Medicare and Medicaid translation requirements.

Consistent with our April 15, 2011 final rule (76 FR 21536), (CMS–4144–F, RIN 0938–AQ00), we continue to claim that the Medicare translation requirement is exempt from the requirements of the PRA since the time, effort, and financial resources necessary to comply with the proposed translation requirements is a usual and customary business practice (see 5 CFR 1320.3(b)(2). For a full accounting of the translation burden, please see section IX.D.3.b. of this proposed rule.

9. ICRs Regarding Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

The following proposed changes will be submitted to OMB for review under control number 0938–1051 (CMS–10260).

We are proposing several changes to the marketing policies in subpart V of parts 422 and 423. Each of these proposed changes would require updates to policies and procedures on the part of a business operations specialist, entailing the addition of a phrase or sentence and, as such, not requiring much time. We will estimate the time required for each proposed regulatory change in this section of this rule. For those instances where we believe the burden to plans is greater than a change to policies and procedures, we will elaborate on what we expect that burden to be.

For our proposed reinstatement of the prohibition on MAOs and Part D sponsors marketing outside of their service areas (unless unavoidable), we estimate ½ hour to implement the change to policies and procedures (.5 hour × $76.20/hour = $38.10).

For our proposed reinstatement of the prohibition on sales presentations following educational events, we estimate ¼ hour to implement the change to policies and procedures (.25 hour × $76.20/hour = $19.05).

For our reinstatement of the prohibition on distribution and collection of Scope of Appointment and Business Reply Cards by agents at educational events, we estimate ¼ hour to implement the change to policies and procedures (0.25 hour × $76.20/hour = $19.05).

For our reinstatement of the prohibition on conducting a sales/marketing or enrollment meeting with a beneficiary before 48 hours after the beneficiary's initial consent to the meeting (via scope of appointment), we estimate ¼ hour to implement the change to policies and procedures (0.25 hours × $76.20/hour = $19.05).

For the clarification of the requirement of a plan to notify CMS of any agent that fails to adhere to CMS requirements, we estimate ½ hour to implement the change to policies and procedures 0(.5 hours × $76.20/hour = $38.10). We estimate that this policy change does have burden, however we have no way of estimating the number of agents and frequency of which they will violate CMS requirements. Therefore, we cannot estimate it. We do, however, solicit industry and more general input on the burden associated with this proposed requirement.

For the requirement that agents/brokers inform beneficiaries that the beneficiaries can obtain complete Medicare information from 1–800–MEDICARE, SHIPs, or Medicare.gov, we estimate ½ hour to implement the change to policies and procedures (0.5 hours × $76.20/hour = $38.10).

For the requirement that agents/brokers ask a standardized list of questions prior to enrolling the beneficiary in a plan, we estimate ½ hour to implement the change to policies and procedures (0.5 hours × $76.20/hour = $38.10). CMS has already developed the questions as part of the Pre-Enrollment Check List. CMS does not require agents/brokers to develop the questions themselves. As the questions were already developed, and the development was by CMS staff, development of the questions does not incur COI burden.

For the requirement that agents/brokers inform beneficiaries of all the plans the agent/broker actually sells, we estimate ¼ hour to implement the change to policies and procedures (0.25 hours × $76.20/hour = $19.05).

For the changes that clarify the prohibition of the use of the term ''Medicare'' or CMS's logos in a way that is misleading or confusing or which misrepresents the plan, we estimate ¼ hour to implement the change to policies and procedures (0.25 hours × $76.20/hour = $19.05).

Thus, the total one-time burden per contract for these marketing provisions is 3.25 hours (0.5 + 0.25 + 0.25 + 0.25

+ 0.5 + 0.5 + 0.5 + 0.25 + 0.25 for the time required to update policies and procedures on the prohibitions of marketing outside the service area, of sales following educational events, of distribution of business cards, as well as the required 48-hour wait time for agents, reporting to CMS delinquent agents, disclosing 800–Medicare, using a standardized list of questions, for agents to notify beneficiaries of all plans they represent, and to avoid misleading use of the Medicare log respectively) at $76.20/hour for a total of $247.65. The aggregate burden across 697 contracts is 2265 hr (3.25 * 697) at a cost of $172,593 ($76.20/hr * 2265 hr).

10. ICRs Regarding Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128)

The following proposed changes will be posted for public review under control number 0938–0964 (CMS–10141) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. The 60-day notice will publish soon after the publication of the final rule (CMS–4201–F).

In the proposed provision, ''Changes to an Approved Formulary'' (see section III.Q. of this proposed rule) we propose to codify guidance in place since early in the Part D program. The burden associated with the negative change request process and notice of negative formulary changes to CMS, affected enrollees, current and prospective enrollees, and other specified entities (as listed in § 423.120(b)(5)(i)) was not accurately captured under the aforementioned OMB control number, which simply included a lump sum of 40 hours per Part D sponsor for a business operations specialist to complete notice requirements to CMS and other entities and did not include notice to affected enrollees. Similarly, the aforementioned control number does not include burden associated with updating the Part D formulary on the Part D sponsor website as required per § 423.128(d)(2)(ii)–(iii). We are now quantifying burden associated with negative formulary changes in a more granular fashion, which includes notice to affected enrollees and online notice by updating the formulary posted on the Part D sponsor website, which we believe to reflect the operational processes which Part D sponsors have been following. As such, we do not believe this reflects added burden for Part D sponsors but rather quantifies the burden that Part D sponsors have been assuming over the course of the Part D program. As noted in section III.Q.1. of this proposed rule, we believe Part D sponsors have been following published guidance since CMS has operational oversight of negative change requests and corresponding formulary updates and we are not aware of significant complaints that beneficiaries are being subjected to negative formulary changes without proper notice.

Immediate formulary changes require advance general notice that such changes may occur at any time. Advance general notice to CMS of immediate substitutions is currently incorporated into annual bid submission workflow as a simple checkbox, which we do not believe has added substantial burden to the overall bid submission process. Language constituting advance general notice of immediate formulary changes (that is, immediate substitutions, positive formulary changes, and market withdrawals) for other specified entities and current and prospective enrollees, is already incorporated into model formulary and evidence of coverage documents and we do not believe our proposed changes would add a substantial burden to preparing the documents outside of the routine annual updates. The burden attributed to the dissemination of Part D plan information is approved under the aforementioned control number at 80 hours annually for each Part D contract's business operations specialist to prepare required plan materials consistent with § 423.128(a), which includes annual updates to the formulary and evidence of coverage documents, among other information. Since language has already been incorporated into the model documents used by Part D sponsors to update their materials and since CMS–10141 has been posted for comment multiple times since the requirements related to advance general notice were codified at § 423.120(b)(5)(iv)(C) (which we are proposing to move to § 423.120(f)(2)), we continue to assume the accuracy of this estimate.

Part D sponsors notify CMS of their intent to make a negative formulary change by submitting a negative change request (NCR) via the Health Plan Management System (HPMS) NCR module. Part D sponsors provide CMS notice of changes which do not require NCRs by submitting updated formulary files during monthly windows, which is a standard formulary management operation. Part D sponsors submit formularies which can be used across multiple contracts and plans. In 2021, CMS approved 551 formularies which were used across 946 contracts and 6,679 plans offered by 206 parent organizations. Since there are some efficiencies with respect to formulary management and NCR submissions (for example, NCRs submitted for one formulary can be applied to others in a streamlined manner), we estimate burden at the parent organization level. However, not all Part D sponsors submit NCRs. In 2021, 136 parent organizations submitted 3,642 NCRs for 321 formularies. We believe that generally a pharmacist is responsible for managing NCR submissions and that each NCR takes approximately 5 minutes (0.0833 hr) to submit through the HPMS module, based on CMS internal user testing. In total, for 136 parent organizations, the burden to submit NCRs is estimated to be 303 hours (3,642 NCRs × 0.0833 hr per NCR) at a cost of $36,621 ($120.86/hr × 303 hr).

Part D sponsors include immediate formulary changes, approved negative changes, and any enhancements (for example, addition of newly approved drugs, moving a drug to a lower cost-sharing tier, removing or making less restrictive utilization management requirements) to their formularies consistent with formulary requirements. Generally, every formulary is updated during these monthly formulary update windows and CMS reviews all changes to ensure they are consistent with regulatory requirements. Since every parent organization generally updates their formulary regardless of whether any negative changes are made, we estimate burden for all 206 parent organizations representing 551 formularies in 2021. There are 11 formulary update windows per year (monthly from January to November). We believe a pharmacist is generally responsible for managing formulary submissions. In this case, 6,061 formulary submissions (551 formularies × 11 submission windows). We estimate that each formulary file update requires 2 hours to prepare, for a total of 12,122 hours (6,061 submissions × 2 hr per submission) at a cost of $1,465,065 (12,122 hr × $120.86/hr).

In addition to notifying CMS in the manner described, Part D sponsors are required to notify other specified entities of formulary changes. As defined in § 423.100, ''other specified entities'' are State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists. Online postings that are otherwise consistent with requirements for notice to other specified entities may constitute sufficient notice of negative formulary changes, although sponsors may use mechanisms other than the

online postings to notify other specified entities of midyear formulary changes as well. Requirements for Part D sponsors' internet website include the current formulary for the Part D plan, updated at least monthly consistent with § 423.128(d)(2)(ii), and advance notice of negative formulary changes for current and prospective enrollees, consistent with § 423.128(d)(2)(iii) as we propose to revise it. To estimate burden associated with providing notice of formulary changes to other specified entities, we calculate the time and cost associated with updating the formulary and providing notice of drugs affected by negative formulary changes (such as a summary table which lists such changes) on the Part D sponsor's website. For 551 formularies in 2021, monthly updates would be posted at least 12 times annually for a total of 6,612 postings (551 formularies × 12 updates/year) by all 206 parent organizations. We estimate that it would take 1 hour to update the website consistent with the requirements at § 423.128(d)(2)(ii) and (iii) and that a computer programmer would be responsible for such postings for a total annual burden of 6,612 hours (6,612 updates × 1 hr/update) at a cost of $614,387 ($92.92/hr × 6,612 hr).

Enrollees affected by negative formulary changes are currently required to receive direct written notice as described at § 423.120(b)(5)(i)(A) and (b)(5)(ii). We propose to move this requirement to § 423.120(f) and (f)(4), respectively. CMS provides a model ''Notice of Formulary Change'' which sponsors may use to meet regulatory requirements. Affected enrollees include those who are subject to immediate substitutions and maintenance formulary changes. The notice requirement is the same, with the exception that enrollees subject to immediate substitutions receive notice retrospectively while enrollees subject to maintenance formulary changes receive notice in advance of the change. Under the proposed rule codifying current operational guidance, there would be no affected enrollees subject to non-maintenance changes since these types of changes would be permitted only when enrollees taking the drug subject to the non-maintenance change are exempt from the change (that is, ''grandfathered'') for the remainder of the contract year. CMS does not collect data on the number of enrollees affected by negative formulary changes. In order to estimate the number of affected enrollees, we used 2021 data on the total number of Part D enrollees (across the entire program) taking each drug subject to the negative formulary change during the contract year. We then calculated the estimated number of affected enrollees by prorating the number of enrollees taking the drug across the entire program based on the relative proportion of the Part D plan's enrollment to the total Medicare Part D enrollment.

The following example illustrates this process. As of December 2021, there were 49,289,670 Part D enrollees. As stated previously, multiple contracts and plans may share the same formulary. A negative formulary change submitted for Drug A on a particular formulary impacted a total of 6 individual plans utilizing this formulary. The total number of Part D enrollees taking Drug A in 2021 was 25,717. The total number of enrollees in the 6 plans implementing the negative formulary change was 40,045, representing 0.0812 percent of the total Part D enrollment (40,045/49,289,670). We then assume that of the 25,717 Part D enrollees taking Drug A during 2021, that 0.0812 percent or 21 enrollees (25,717 × 0.000812) were affected by the negative formulary change. This logic was applied across all immediate substitutions and maintenance formulary changes submitted during 2021. We do not estimate enrollees affected by market withdrawals since these occur infrequently and unpredictably (historically occurring every few years) and the number of enrollees affected could vary substantially depending on the drug implicated.

In total, there were 164 parent organizations that implemented immediate substitutions or maintenance formulary changes for 379 formularies used for 576 contracts and 3,735 plans affecting a total of 65,535 enrollees. We do not attribute substantial burden associated with incorporating the model notice into Part D sponsors' internal systems for mailing, since this would have been a one-time initial upload with minor updates annually. We therefore calculate non-labor costs associated with sending notice of formulary change to affected enrollees. Enrollees may opt in to receiving communication materials electronically rather than via hard-copy mailings; however, consistent with informal communication from stakeholders for other required documents, we assume all affected enrollees prefer hard-copy mailings. Costs for hard-copy mailings include paper, toner, and postage.

- *Cost of paper:* We assume $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).
- *Cost of toner:* We assume a cost of $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).
- *Cost of postage:* The cost of first-class metered mail is $0.57 per letter up to 1 ounce. We are using metered mail because these notifications contain confidential beneficiary information and therefore a bulk mailing cannot be used.

++ A sheet of paper weights 0.16 ounces (5 pounds/500 sheets × 16 ounces/pound). We estimate each mailing to consist of 2 pages or 0.32 ounces, so no additional postage for mailings in excess of 1 ounce is anticipated.

Thus, the aggregate cost per mailing is $0.598 ([$0.007 for paper × 2 pages] + [$0.007 for toner × 2 pages] + $0.57 for postage). We estimate the total annual mailing cost at $39,190 ($0.598 per notice × 65,535 affected enrollees).

The summary of burden, labor and non-labor costs, associated with this provision is summarized in Table 9.

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TABLE 9 CHANGES TO AN APPROVED FORMULARY

Regulatory Citation	Response Summary	Total Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Wage ($/hr)	Total Annual Cost ($)
Current: §423.120(b)(6)(ii)(A)(*1*) Proposed: §423.120(e)(1)	Submit Negative Change Request	136	3,642	0.0833	303	120.86	36,621
Current: §423.120(b) Proposed §423.120(f)	Update Formulary in HPMS	206	6,061	2	12,122	120.86	1,465,065
No Proposed Change: §423.128(d)(2)(ii)-(iii)	Updating Formulary and Providing Online Notice of Changes on Website	206	6,612	1	6,612	92.92	614,387
Current: §423.120(b)(5)(i)(A) and (b)(5)(ii) Proposed: §423.120(f) and (f)(4)	Direct Written Notice to Affected Enrollees	164	65,535	n/a	n/a	n/a	39,190*
TOTAL		206	81,850	Varies	19,037	Varies	2,155,263

*Non-labor cost.

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11. ICRs Regarding Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d))

The following proposed changes will be submitted to OMB for review under control number 0938–1154 (CMS–10396).

Based on analyses conducted on MTM plan-reported and validated beneficiary-level data from 2020, CMS proposes the following combination of changes to the MTM program targeting criteria:

- Requiring plan sponsors to target all core chronic diseases, and continuing to allow them to add other chronic diseases;
- Codifying the current 9 core chronic diseases in regulation and adding HIV/AIDS, for a total of 10 core chronic diseases;
- Lowering the maximum number of covered Part D drugs, a sponsor may require from 8 to 5 drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and
- Revising the annual cost threshold ($4,935 in 2023) methodology to be based on the average annual cost of 5 generic drugs ($1,004 in 2020);

Taken together, we estimate that these proposed changes would increase the number (and percentage) of Part D beneficiaries eligible for MTM services by 6,485,066 from 4,508,762 (9 percent of all Part D beneficiaries) to 10,993,828 (22.93 percent of all Part D beneficiaries). While we considered multiple alternative proposals, we ultimately proposed this combination of changes as a way to close significant gaps in MTM eligibility while balancing program size and burden on Part D sponsors.

Under § 423.153(d), all MTM enrollees must be offered a 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. Under § 423.153(d)(1), plans are required to provide all enrollees targeted for MTM services with information about safe disposal of prescription medications that are controlled substances. Plans may mail this information as part of the CMR summary, a TMR, or other MTM correspondence or service. In this section we are estimating the additional burden that would be placed on plan sponsors to conduct CMRs (labor cost) and mail the written CMR summaries (non-labor cost) to the additional beneficiaries that would be targeted for MTM programs based on our proposed revisions. We also estimate the cost of sending safe disposal information to the beneficiaries who would be newly targeted under these revised criteria, but do not receive a CMR.

To obtain aggregate burden we separately estimate: (1) the burden for pharmacists to complete the CMR; (2) the mailing costs of the CMRs; and (3) the cost of mailing of safe disposal instructions to those targeted beneficiaries who did not accept the offer of a CMR.

- The burden for pharmacists to complete the CMR: Based on internal data, we found 63.6 percent of MTM program enrollees accepted the offer of a CMR in 2020. To estimate the cost of conducting the additional CMRs, we multiply the expected number of additional MTM program enrollees (6,485,066) by 0.636 to obtain the number of additional CMRs we estimate will actually be conducted (4,124,502). We estimate a pharmacist would take 40 minutes (0.6667 hr) at $120.86/hr to complete a CMR. Thus, the total burden is 2,749,805 hours (0.6667 hr/CMR * 4,124,502 enrollees who accept the CMR offer) at a cost of $332,341,432 (2,749,805 hr * $120.86/hr).
- Mailing Costs of CMRs. To estimate the cost of sending the CMR summaries, we assume that the average length of a CMR is 7 pages (including 1 page for information regarding safe disposal). Therefore, the first class postage costs $0.81 per metered mailing. Paper costs are $0.007 per sheet ($3.50 per ream/500 sheets per ream) and toner costs $70.00 per cartridge and lasts for 10,000 sheets (at $0.007 per sheet = $70.00/10,000 sheets). Thus, the total cost per CMR mailing is $0.908 ($0.81 postage + [7 sheets/CMR * $0.014]. Therefore, the annual cost of mailing CMRs to the additional 4,124,502 beneficiaries expected to accept the CMR offer is $3,745,048 (4,124,502 enrollees × $0.908/mailing).
- *Mailing costs for safe disposal information:* Out of the 6,485,066 additional beneficiaries expected to be targeted for MTM based on the revised criteria, we expect that 36.4 percent or 2,360,564 (6,485,066 * 0.364) will decline a CMR. These enrollees will still need to receive information regarding the safe disposal of prescription drugs that are controlled substances. For purposes of calculating the burden, we are assuming that any safe disposal information that is not included in a CMR is either (1) being mailed in a TMR, which may be as short as one page and may contain private health information; or (2) is mailed as a stand-alone document which does not contain any private health information. For purposes of impact, (1) if one additional page is included in the TMR, then there is no additional postage; and (2) if the safe disposal information is mailed separately, there would be no private health information, and the burden would be the cost of one page plus bulk postage. Due to a lack of data with regard to what percentage of safe disposal information will be mailed as part of a TMR or other MTM correspondence or service, we are assuming that all safe disposal information not sent with a CMR will be one page that is mailed separately using bulk postage in order to project the maximum cost of such mailing. The cost to mail one page of safe disposal information is $0.015 per enrollee if the letter does not contain private health information and thus bulk mailing is used (1 page $0.007/sheet) + (1 page × $0.007 toner) + ($0.20/200 items for bulk postage). Therefore, we estimate that the cost of mailing safe disposal information to those beneficiaries targeted for MTM who do not receive it in a CMR summary is $35,408 ($0.015 × 2,360,564).

Therefore, the total burden associated with the proposed revisions to the MTM targeting criteria is 2,749,805 hours and $336,121,888 ($332,341,432 for a pharmacist to produce the CMRs for beneficiaries newly targeted for MTM under the proposed revised criteria + $3,745,048 to mail the CMR written summary in the CMS standardized format with safe disposal information + $35,408 for mailing information regarding safe disposal to beneficiaries newly targeted for MTM who do not receive a CMR).

12. ICRs Regarding Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 401.305(a)(2), 422.326(c), and 423.360(c))

The proposed amendments to §§ 401.305(a)(2), 422.326(c), and 423.360(c) would change the standard for an ''identified overpayment'' for Medicare Parts A, B, C, and D and adopt by reference, the knowledge standard set forth in the False Claims Act at 31 U.S.C. 3729(b)(1). The proposed amendments for Medicare Parts A and B are associated with OMB control number 0938–1323 (CMS–10405); however, we are not making any revisions to the currently approved requirements and burden under this

control number. The proposed amendments for Medicare Parts C and D are associated with OMB control number 0938–1152 (CMS–10340) and OMB control number 0938–0878 (CMS–10062); however, we are not making any revisions to the currently approved requirements and burden under either of these control numbers. Although we cannot predict if there will be any change in the number of overpayments identified or reported under the proposed amendments to the rule, we solicit comment on this assumption.

13. ICRs Regarding Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

MA organizations that offer special needs plans are currently effectuating involuntary disenrollments for loss of special needs status as part of existing disenrollment processes, including the member notifications outlined in our proposal; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for these member notifications has not previously been submitted to OMB, due to inadvertent oversight, we are seeking OMB approval under the aforementioned OMB control number.

We are proposing to codify current policy on MA plan notices prior to a member disenrollment for loss of special needs status. MA organizations would be required to provide the member a minimum of 30 days advance notice of disenrollment regardless of the date of the loss of special needs status. Additionally, the organization would be required to provide the member a final notice of involuntary disenrollment, sent within 3 business days following the disenrollment effective date, and before the disenrollment transaction is submitted to CMS.

Where an individual is involuntarily disenrolled from an MA plan for any reason other than death, loss of entitlement to Part A or Part B, the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual, pursuant to § 422.74(c). The notice requirement in § 422.74(c) is currently approved by OMB under the aforementioned control number.

To estimate the number of notices required due to involuntary disenrollments for loss of special needs status, we determined the average number of annual disenrollments due to loss of special needs status. Between 2017 and 2021, there were an average of 55,127 involuntary disenrollments per year due to loss of special needs status.

We estimate that it would take each MA organization 1 minute (0.017 hr) to assemble and disseminate the advance notice, 5 minutes (0.083 hr) to submit the required transaction to CMS for each disenrollment, and 0.017 hr to assemble and disseminate the final notice for each disenrollment. Therefore, the total annual time for each MA organization is 0.1170 hours (0.017 hr + 0.083 hr + 0.017 hr).

We estimate the aggregate annual burden for all MA organizations to process these disenrollments to be 6,450 hours (55,127 disenrollments * 0.117 hr) at a cost of $491,490 (6,450 hr * $76.20/hr).

14. ICRs Regarding Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74(b)(2))

The requirement proposed at § 422.74(b)(2)(vii) to establish a process for involuntary disenrollment for an individual who loses eligibility mid-year to be enrolled in an MA MSA plan, and more specifically, the requirement for the MA organization to give the individual a written notice of the disenrollment at § 422.74(c) with an explanation of why the MA organization is planning to disenroll the individual, will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

The annual burden associated with this requirement consists of the time and cost to notify the individual and CMS. Based on the active burden in CMS–R–267, we estimate that each disenrollment will require 1 minute (0.017 hr) for the MA MSA plan to notify CMS and 5 minutes (0.083 hr) for the MA MSA plan to notify the individual. Thus, the total burden per disenrollment is estimated at 6 minutes (0.1 hr) (1 minute to assemble and disseminate the notice to CMS and 5 minutes to assemble and disseminate the notice to the individual) at a cost of $7.62 (0.1 hr × $76.20/hr for a business operations specialist to perform the work).

To obtain aggregate burden we used data from 2019 and 2021 in which there were an average of 4 MSA contracts. We used an average since the data had no visible trend but hovered around a central value. There was an average of 8,624 enrollees during 2019–2021 and the average disenrollment was 124. Thus, we estimate an aggregate burden of 12 hours (124 disenrollments * 0.1 hr. per disenrollment) at a cost of $914 (12 hr * $76.20/hr).

15. ICRs Regarding Required Notice for Reinstatements Based on Beneficiary Cancellation of New Enrollment (§§ 422.60 and 423.32)

The following proposed changes will be submitted to OMB for review under control number 0938–1378 (CMS–10718).

CMS's subregulatory guidance currently provides that MA and PDP plans send notification of enrollment reinstatement based on the cancellation of enrollment in a new plan. Our proposal would not add to existing reinstatement processes; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for these enrollment reinstatement notifications has not previously been submitted to OMB, we aim to correct that oversight by requesting OMB's review and approval under the aforementioned control number.

We are proposing to codify CMS's current policy that plans notify an individual when the individual's enrollment is reinstated due to the individual's cancellation of enrollment in a different plan. The MA or PDP plan from which the individual was disenrolled would be required to send the notification of the enrollment reinstatement within 10 days of receipt of Daily Transaction Reply Report (DTRR) confirmation of the individual's reinstatement. The reinstatement notice would include confirmation of the individual's enrollment in the previous plan with no break in coverage, plan-specific information as needed, and plan contact information.

To estimate the number of reinstatement notices required due to an individual's cancellation of enrollment in a new plan, we determined the number of annual reinstatements based on the cancellations of enrollment in a new plan. In 2021, there were 5,686,989 disenrollments from MA and MA–PD plans due to enrollments in another plan and 4,292,426 disenrollments from PDP plans due to enrollments in another plan. Further, between 2017 and 2021, there was an average of 193,183 cancelled enrollments per year in a new MA plan (including MA–PD plans). Between 2017 and 2021, there was an average of 32,723 cancelled enrollments per year in a new PDP plan. Each cancelled enrollment in a new plan results in a reinstatement notice sent to the beneficiary. Thus, we estimate 225,906 (193,183 + 32,723) reinstatements annually.

We estimate that it would take 1 minute (0.017 hr) at $76.20/hr for a MA or PDP plan's business operations

specialist to assemble and disseminate the notice for each reinstatement. In aggregate, we estimate an annual burden of 3,840 hours (225,906 reinstatements * 0.017 hr) at a cost of $292,608 (3,840 hr * $76.20/hr).

16. ICRs Regarding Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors That Are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§ 422.500, 422.528, 422.529, 423.501, 423.521, and 423.522)

The following proposed changes will be submitted to OMB for review under control number 0938–1054 (CMS–10261).

In this rule, proposed §§ 422.528, 422.529, 423.521, and 423.522 would increase burden by requiring that MA organizations and Part D sponsors who disagree with the CMS calculated final settlement amount appeal the final settlement amount, if any, for each contract that consolidates, non-renews, or terminates. There is also additional burden requiring that MA organizations and Part D sponsors respond directly to CMS. The response consists of those MA organizations and Part D sponsors requesting an appeal of the final settlement amount and filing a written request for reconsideration with CMS that includes the specific calculations with which the MA organization or Part D sponsor disagrees and any relevant evidence to support a belief that the CMS final settlement amount may have been calculated incorrectly.

In amended paragraphs §§ 422.500 and 423.501 of this proposed rule, we proposed to define final settlement amount and outline the proposed final settlement process which consists of: (1) CMS calculating the final settlement amount of any payment to be disbursed to, or collected from, an MA organization or Part D sponsor whose contract with CMS has been consolidated into another contract, non-renewed, or terminated; (2) CMS communicating to the MA organization or Part D sponsor the final settlement amount and any relevant information MA organizations and Part D sponsors need to validate the final settlement amount; and (3) final actions needed to be taken by CMS, MA organizations, and Part D sponsors to make payments to or receive final payments from CMS. The final settlement amount is calculated by summing final retroactive payment adjustments that accumulated after a contract ceased operation and all final applicable reconciliations including MLR remittances (described in §§ 422.2470 and 423.2470), Coverage Gap Discount Program (described in § 423.2320), Part D annual reconciliation (described in § 423.343), and final risk adjustment reconciliation (described in § 422.310).

Under the current policy, CMS would send a notice, referred to as the notice of final settlement, to MA organizations and Part D sponsors with contracts that are consolidating, non-renewing, or terminating containing information on final settlement. The notice of final settlement contains (1) the final settlement amount; (2) relevant CMS banking and financial mailing information; (3) relevant CMS contact information and; (4) information for MA organizations and Part D sponsors regarding the steps for requesting a review of the final settlement amount calculation.

Historically, on average, for the period 2015 through 2020, CMS sent 47 letters annually and received 3 responses, which typically requested that CMS validate the final settlement amount.

We are proposing at new paragraphs §§ 422.528(b) (for MA) and 423.521(b) (for Part D) to require MA organizations and Part D sponsors that disagree with the final settlement amount request an appeal of the final settlement amount within 15 days of the date of issuance of the notice of final settlement.

Whereas under current CMS processes, we allow MA organizations and Part D sponsors to submit evidence supporting a review request on a case-by-case basis, proposed §§ 422.529 and 422.522 specify that MA organizations and Part D sponsors specify the calculations with which they disagree and provide evidence supporting the assertion that CMS's calculation of the final settlement amount described in the notice of final settlement is incorrect.

In calculating the burden of this proposal, we assume the following:

- 44 contracts, on average, will accept the CMS final settlement amount upon issuance of the notice of final settlement.
- 3 contracts will disagree with the CMS decision and request a review of the final settlement amount calculation.
- Burden is distributed between business operations specialists working at $76.20/hr and Medical and Health managers working at $115.21/hr, who perform a quality review of data and draft a response to CMS on behalf those MA organizations or Part D sponsors who disagree with the CMS calculated final settlement amount.
- The primary tasks of business operations specialists are to gather and validate data, determine the accuracy of the final settlement amount calculation, and draft a response.
- The primary task of the managers is to quality assure the work of the business operations specialist.

The time for MA organizations and Part D sponsors is based on the effort needed to access and analyze data in order to validate the CMS final settlement amount and provide aa request for a reconsideration. Any other burden was not considered in this analysis. For example, under proposed §§ 422.529 and 423.522, we explain that CMS will not accept, as part of the final settlement process or review, any new information that would be used for adjusting the applicable reconciliations and that the final settlement amount determined after a CMS review is final. Should a Part D sponsor request a review of the final settlement amount because of a belief that the Part D annual reconciliation was calculated inaccurately, that review would be denied because CMS will not be redetermining reconciliation amounts, and any burden associated with that request was not included in this analysis.

In estimating time, we separately consider the 44 contracts that we expect to agree with the CMS decision and the 3 contracts that we expect to request a review. Besides calculating total costs by considering each case, we also calculate a single summary line for the summary table, by dividing total burden by the 47 contracts Table 10 summarizes all burden estimates which could be useful in reviewing the bullets that follows this table. Explanatory comments for the line items in Table 10 are presented below it.

Table10: Summary of Aggregate Burden For Final Settlement

Group	Routine Responses	Disagreeing Responses	Total Responses	
Number of contracts in Group	44	3	47	
Task	Time Needed (hr)	Time Needed (hr)	Wages ($/hr)	Total Cost over 47 contracts (44 routine + 3 disagreeing)
Validation	4	4	76.20 (BOS)	$14,335 = $305 (4 * $76.20 hr) * 47
Drafting a response		3	76.20 (BOS)	$686 (3 contracts * 3 hr/contract *$76.20/hr)
Quality Review		2	115.22 (Manager)	$691 (3 contracts * 2 hr/contract * $76.20/hr
Total	4	9		$15,712

- Staff time for validating data (hours): For the 47 contracts (44 routine + 3 disagreeing) receiving a notice of final settlement from CMS, which contains the information CMS used to calculate the final settlement amount, we expect each of the 47 contracts to spend 4 hours validating CMS data.
- Staff time for drafting a response (hours): For the 44 contracts agreeing with CMS, no drafting of a response is required. However, for the 3 contracts disagreeing with CMS, we estimate 3 hours of work to develop a summary of the disagreement and compile any relevant evidence for CMS. Thus the aggregate burden for the 3 disagreeing contracts is $686 (3 contracts * 3 hr/contract * $76.20/hr) for drafting a response.

We next perform a similar burden analysis to arrive at the aggregate cost.

- For each of the 47 contracts, a business operations specialist working for 4 hours validating the final settlement amount at $76.20/hr would incur a burden of $305 (4 hr * $76.20/hr). Therefore the aggregate burden over all 47 contracts is $14,335 (47 contracts * $305)
- For the 3 contracts disagreeing with the CMS decision, a business operations specialist working for 3 hours drafting a response at a cost of $76.20/hr incurs an aggregate burden of $686 (3 contracts * 3 hours/contract * $76.20/hr)
- For the 3 contracts disagreeing with CMS, a manager working for 2 hours at a cost of $115.22/hr would incur a burden of $$691 (3 contracts * 2 hours * $115.22).
- The aggregate burden over all contracts is 203 hours (44 routine contracts * 4 hours for validation + 3 disagreeing contracts * 5 hours (3 hr to write a summary report + 2 hr for quality review) at an aggregate cost of $15,712 (($14,355 for 47 validations + $686 for 3 contracts to write a summary + $691 for 3 contracts to perform a quality review)

The per contract burden differs for the 44 routine contracts and the 3 disagreeing contracts. For the 44 routine contracts the per contract burden is 4 hours to perform a validation at a per contract cost of $305. For the 3 disagreeing contracts the per contract burden is 9 hours (4 hours for validation + 3 hours for writing a summary + 2 hours for performing a quality review) at a per contract burden of $1,682 ($305 for validation + $686 for writing a report + $691 for performing a quality review).

17. ICRs Regarding Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

As described in section V.G. of this proposed rule, we are proposing to add, remove, and update certain measures, to replace the current reward factor with a new HEI reward to further incentivize Part C and D plans to focus on improving care for enrollees with specific SRFs, to reduce the weight of patient experience/complaints and access measures, to remove guardrails when determining measure-specific-thresholds for non-CAHPS measures, to modify the hold harmless policy for the current improvement measures, to add a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, and to remove the 60 percent rule that is applied when adjusting Star Ratings for extreme and uncontrollable circumstances (for example, natural disasters like hurricanes or public health emergencies). The proposed HEI is a different way for CMS to analyze existing data and would not increase plan burden. Most of the new measures would be calculated from administrative data and, as such, there would be no increase in plan burden. The other measure-level changes entail moving existing measures from the display page to Star Ratings, which also would have no impact on plan burden. We are also proposing a series of technical clarifications related to adjusting Star Ratings for extreme and uncontrollable circumstances, QBP appeals processes, consolidations, and weighting of measures with a substantive specification change. The proposed provisions will not change any respondent requirements or burden pertaining to any of CMS's Star Ratings related PRA packages, including: OMB control number 0938–0732 for CAHPS (CMS–R–246), OMB control number 0938–0701 for HOS (CMS–10203), OMB control number 0938–1028 for HEDIS (CMS–10219), OMB control number 0938–1054 for Part C Reporting Requirements (CMS–10261), OMB control number 0938–0992 for Part D Reporting Requirements (CMS–10185), and OMB control number 0938–1129 for Appeals of Quality Bonus Payment Determinations (CMS–10346). Since the provisions will not impose any new or revised information collection requirements or burden, we are not proposing to make changes under any of the aforementioned control numbers.

18. ICRs Regarding Personnel Requirements Under PACE (§§ 460.64 and 460.71)

The following proposed changes will be submitted to OMB for review under control number 0938–0790 (CMS–R–244).

Section 460.64 currently includes the requirements relating to the qualifications of PACE personnel who have direct contact with PACE participants. This includes the requirement that PACE organizations medically clear personnel of communicable diseases. As discussed in section VI.E. of this proposed rule, PACE organizations are currently required to ensure staff (employees and contractors) are free of communicable diseases. We proposed to allow PACE organizations the option to create and implement a risk assessment tool to assist with this medical clearance process. Therefore, we estimate there will be a one-time burden for PACE organizations associated with these new requirements to update policies and procedures related to medical clearance, and when applicable, to develop a risk assessment tool. We believe the compliance officer and primary care physician (PCP) would be responsible for ensuring the necessary materials are updated, for determining medical

clearance, and developing the risk assessment tool. For revising policies and procedures related to medical clearance, we estimate it would take 1 hour at $72.90/hr for a compliance officer at each PACE organization to update these materials. For the development of the risk assessment tool, we estimate it would take each PACE organization 5 hours consisting of: 4 hours of work by the compliance officer at $72.90/hr and 1 hour of work by the PCP at $232.88/hr. The weighted hourly wage for the compliance officer and PCP to update policies and procedures to create a risk assessment is $104.90/hr (((4 hr * $72.90/hr) + (1 hr * $232.88/hr))/5 hr of aggregate burden).

In aggregate, we estimate a one-time burden of 149 hours (149 PACE organizations [225] * 1 hr) at a cost of $10,862 (149 hrs * $72.90/hr) for the development of policies and procedures.

To develop a risk assessment tool, we also estimate a one-time burden of 745 hours (149 PACE organizations * 5 hrs) at a cost of $78,151 (745 hrs * $104.90/hr) for both the compliance officer and PCP roles in developing the risk assessment tool.

19. ICRs Regarding Service Delivery Under PACE (§ 460.98)

The following proposed changes will be submitted to OMB for review under control number 0938–0790 (CMS–R–244).

Section 460.98 currently includes requirements related to delivery of services to PACE participants. This includes the minimum requirements for the provision of services PACE organizations must provide and how the services must be furnished. The current requirement that PACE organizations must provide all necessary services to meet the needs of participants as expeditiously as the participant's health conditions require would not change with this proposed rule, but as discussed in section VI.G. of this proposed rule, we are proposing to add required timeframes for arranging and scheduling services for PACE participants. We believe there will be a one-time burden for PACE organizations to update their policies and procedures to reflect the proposed timeframes. We believe the compliance officer will be responsible for updating the policies and procedures. We estimate that it would take the compliance officer 1 hour at $72.90/hr to update the necessary materials. Therefore, we estimate a one-time burden of 149 hours (149 PACE organizations * 1 hr) at a cost of $10,862 (149 hrs * $72.90/hr).

20. ICRs Regarding PACE Participant Rights (§ 460.112)

The following proposed changes will be submitted to OMB for review under control number 0938–0790 (CMS–R–244).

Section 460.112 currently includes the specific rights to which PACE participants are entitled. As discussed in section VI.J. of this proposed rule, we are proposing to add new participant rights and modify existing participant rights to enhance participant protections. Specifically, we are proposing to add and/or modify the rights to appropriate and timely treatment; to be fully informed, in writing, of different treatment options including palliative, comfort, and end-of-life care; to fully understand the PACE organization's palliative, comfort, and end-of-life care services; and to request services from the PACE organization through the process described in § 460.121. PACE organizations are currently required to provide a copy of the participant rights listed in § 460.112 to participants at the time of enrollment, and to post a copy of the rights in the PACE center. If our proposed changes to § 460.112 are finalized, PACE organizations would be required to revise the materials they provide to participants at the time of enrollment and the posting in the PACE center to account for the new and modified requirements. Therefore, we estimate a one-time burden for PACE organizations to update the participant rights included in the enrollment information and post the new participant rights in PACE centers. We believe it would take a compliance officer 2 hours at $72.90/hr to update these materials.

The PACE organizations would also be required under this proposal to develop written templates explaining palliative care, comfort care, and end-of-life care services. We believe the development of these materials is a one-time burden and would take a compliance officer 2 hours to complete at $72.90/hr.

In aggregate, we estimate a one-time burden of 596 hours (149 PACE organizations * (2 hrs + 2 hrs)) at a cost of $43,448 (596 hrs * $72.90/hr).

We also estimate this provision would result in increased ongoing costs to PACE organizations. As discussed in section VI.J. of this proposed rule, we are proposing to require PACE organizations to provide participants with written documentation explaining the different treatment options including palliative, comfort, and end-of-life care services. Specifically, we are proposing to require PACE organizations to describe their palliative care, comfort care, and end-of-life care services and how they differ from the care the participant is currently receiving; whether these treatment options will be provided in addition to or in lieu of the care the participant is currently receiving; a detailed description of all services that will be impacted and how they will be impacted if the participant and/or designated representative elects to initiate a different treatment option; and that the participant has the right to revoke or withdraw their consent to receive these treatment options at any time and for any reason.

We estimate that a registered nurse (RN) will need to tailor written templates for each participant based on the treatment option they choose and the impact that treatment option will have on their current services. We estimate it would take the RN 1 hour to tailor the written template to each participant at $79.56/hr. We also estimate the Master's-level Social Worker (MSW) would either provide the materials in person to the participant and/or their designated representative or they would mail the materials to the participant. We estimate it would take the MSW 10 minutes (0.1667 hr) to mail or present the materials to each participant at $59.92/hr.

We are also proposing that PACE organizations must explain the treatment options to participants and/or their designated representatives before palliative care, comfort care, or end-of-life care services can be initiated. This includes fully explaining the treatment options, providing the participant and/or designated representative with the written materials discussed previously, and obtaining written consent from the participant and/or designated representative. We estimate it would take the MSW 1 hour at $59.92/hr to explain the services and answer any questions the participant and/or designated representative might have.

To estimate the increased burden, we use the following assumptions about the number of participants who may pursue palliative care, comfort care, and/or end-of-life care services, based on our experience monitoring and auditing PACE organizations. We estimate that 2 out of every 10 participants in a given year (20 percent) will require written materials for palliative care, comfort care, or end-of-life care services. The total national enrollment in PACE as of

[225] Number of PACE organizations is current as of September 20, 2022.

September 2022 was 54,637 [226] with 149 active PACE organizations.

For tailoring information within the written templates and providing written materials to participants as specified at proposed § 460.112(c)(5), we estimate ongoing burden using the weighted hourly wage for the RN and MSW. The weighted average can be obtained as follows. The total cost per participant is $89.55/hr [(1 hr * $79.56/hr (RN)) + (0.1667 hr * $59.92/hr (MSW))]. The total time is 1.1667 hours (1 hr for the RN plus 0.1667 hr the MSW). Thus, the average hourly wage is $76.75/hr (total cost of $89.55/1.1667 hr).

Using these assumptions, we estimate the ongoing burden for proposed requirements at § 460.112(c)(5) would affect 10,927 participants (20 percent of participants who are expected to need end-of-life explanations * 54,637 participants). Therefore, to tailor and mail materials there is an annual burden of 12,749 hours (10,927 affected participants * 1.1667 hr) at a cost of $978,486 (12,749 hr * $76.75/hr).

We estimate an ongoing burden for PACE organizations' MSW to explain treatment options to participants as specified at § 460.112(e)(2) to be 10,927 hours ((54,637 participants * 20 percent participants who require materials) * 1 hr) at a cost of $ 654,746 (10,927 hr to discuss treatment options * $59.92/hr).

In aggregate, we estimate a one-time burden of 596 hours (149 PACE organizations * (2 hrs + 2 hrs)) at a cost of $43,448 (596 hr * $72.90/hr) and an annual ongoing burden of 23,676 hours (12,749 hrs + 10,927 hrs) at a cost of $1,633,232 ($978,486 + $654,746).

21. ICRs Regarding PACE Grievance Process (§ 460.120)

The following proposed changes will be submitted to OMB for review under control number 0938–0790 (CMS–R–244).

Section 460.120 currently includes the grievance process PACE organizations are required to follow. As discussed in section VI.K. of this proposed rule, PACE organizations are already required to develop procedures on processing grievances, and provide notification of the grievance process to participants upon enrollment and at least annually; however, our proposed changes would require the PACE organization to update those procedures. Additionally, we are proposing that written or oral notification must include such as a summary of the issues, a summary of the findings, the steps taken to investigate the grievance (if applicable), and the corrective actions taken (if applicable). Our proposal, which adds requirements on what must be included in grievance resolution notifications, would require the PACE organization to revise and update their notification templates. Therefore, we estimate a one-time burden for PACE organizations to update their materials to meet these new requirements. We do not believe the proposed changes to § 460.120 will impact the annual hours of burden for PACE organizations, because they are already required provide notification of grievance resolutions to participants, and may opt to do so orally or in writing. Therefore, we believe that the ongoing burden will not change with this proposal.

For the one-time burden for updating policies and procedures, we estimate that it would take the compliance officer 2 hours to update these materials at $72.90/hr. For the revised notification of the grievance process, that is provided both upon enrollment and at least annually, we estimate it would take the compliance officer 1 hour to revise these notifications at $72.90/hr. For the written grievance resolution notification, we estimate it will take the compliance officer 1 hour to revise the written resolution notification at $72.90/hr.

In aggregate, we estimate it would take PACE organizations 596 hours [149 PACE organizations * (2 hrs + 1 hr + 1 hr)] at a cost of $43,448 (596 hrs * $72.90/hr).

22. ICRs Regarding the PACE Service Determination Process (§ 460.121)

The following proposed changes will be submitted to OMB for review under control number 0938–0790 (CMS–R–244).

Section 460.121 currently includes the service determination process PACE organizations are required to follow and only allows PACE organizations to notify participants and/or their representatives of service determination extensions in writing. Per the burden estimate that is currently seeking OMB approval under the process (August 5, 2022; 87 FR 48030), we estimate the burden of the current extension notification requirements at § 460.121 to be 2,350 hours and $140,812 in aggregate. As discussed in section VI.L. of this proposed rule, we are proposing to allow PACE organizations to notify the participant or their designated representative either orally or in writing when the PACE organization extends the timeframe for making a service determination. Under this proposal, we expect that PACE organizations will prefer to provide oral notification more frequently than written notification, because oral notification is less time consuming. In anticipation of PACE organizations' preference for oral notification over written notification and the 45 minutes per response reduction in burden oral notification offers, we estimate that the proposed changes will reduce the burden of the extension notification requirements at § 460.121.

To estimate the decreased burden, we considered: (1) the annual number of extension notifications; (2) the estimated proportions of extension notifications that are provided orally or in writing; and (3) the estimated time required to complete oral and written notification.

First, we reviewed extended service determination requests (SDRs) from 2019 through 2021 and found that there were 6,564 total extended SDRs nationally (3,942 in 2019 + 773 in 2020 + 1,849 in 2021). Then we averaged the number of extended SDRs from 2019–2021 to calculate 2,188 extended SDRs annually (6,564 total extended SDRs/3 years), which is about 15 extended SDRs per PACE organization annually (2,188 extended SDRs annually/149 PACE organizations).

Secondly, we estimate, based on our experience with audits of similar areas of PACE requirements where PACE organizations have an option of oral or written notification, that 80 percent of extension notifications will be provided orally, at 15 minutes per notification, and 20 percent will be provided in writing at 1 hour per notification. The hourly wage for notification by an MSW in both cases is $59.92/hr. In aggregate, the new burden would be 875 hours ((2,188 extension notifications * 0.2 written notifications * 1 hr) + (2,188 extension notifications * 0.8 oral notifications * 0.25 hr)) at a cost of $52,430 (875 hrs * $59.92/hr).

Thus, the aggregate annual time and cost savings for the proposed changes are minus 1,475 hours (2,350 hr under current provisions minus 875 hr as documented in the pending OMB package) and minus $88,382 ($140,812 cost under current provisions minus $52,430 under the pending OMB package). Additionally, at the individual service determination request extension level, PACE organizations that choose to provide oral notification instead of written notification will save minus 0.75 hours and $44.94 per extension notification.

[226] This total was accurate as of September 20, 2022.

23. ICRs Regarding PACE Participant Notification Requirement for PACE Organizations With Past Performance Issues or Compliance Deficiencies (§ 460.198)

The following proposed changes will be submitted to OMB for review under control number 0938–0790 (CMS–R–244).

In this proposed rule, CMS proposes to add a new provision, § 460.198, which would give CMS the authority to, at its discretion, require a PACE organization to disclose to its PACE participants or potential PACE participants, the PACE organization's performance and contract compliance deficiencies in a manner specified by CMS. The purpose of this proposal is to enable CMS to better protect PACE participants by ensuring that PACE participants and their caregivers have adequate information to make informed decisions regarding the PACE organization.

The overall PACE organization burden of this requirement is expected to be minimal. In the past, CMS has only required organizations to send these notices to enrollees when CMS sanctioned the organization, which is an extremely rare occurrence. Regarding PACE organizations, between CY 2019 and 2021, CMS sanctioned a total of 3 PACE organizations for an average of 1 per year. As a result, CMS projects that between one and two PACE organizations per year would be required to notify participants and potential participants of their performance and contract compliance deficiencies. In addition, CMS would provide the PACE organization with a template of what to include in the notice, and organizations have the capability to send notices to participants. Therefore, we estimate a burden for PACE Organizations to complete and send the template to participants and potential participants.

For the annual burden for completing the template and sending it to participants and potential participants, we estimate that it would take the compliance officer at the PACE organization 1 hour to complete and send out the template (which would be automated) at $72.90 per hour. In aggregate, we estimate it would take PACE organizations 2 hours (2 PACE organizations * (1 hr) at a cost of $146 (2 hrs * $72.90/hr).

24. ICRs Regarding Safeguarding Data and Records and Medical Record Requirements (§§ 460.200 and 460.210)

PACE organizations are currently required to retain original communications related to a participant's care, health, or safety in the medical record. In this proposal, we are removing the requirement that these communications be stored in the participant's medical record, provided certain conditions are met. Therefore, our burden estimates include costs incurred related to staff (1) training; (2) software development; (3) file cabinets for document storage; and (4) updating/maintaining the organizations' policies and procedures.

- *Training:* We estimate that a PACE organization will spend 40 hours at a cost of $2,916 (40 hr × $72.90/hr) for a compliance specialist to establish training materials. In aggregate, we estimate a one-time burden of 5,960 hours (40 hours × 149 POs) at a cost of $434,484 (5,800 hr. × $72.90/hr).
- *Software development:* We estimate that PACE organizations will spend 40 hours at a cost of $4,654 (40 hours × $116.34/hr) for a software developer to make the appropriate software updates. In aggregate, we estimate a one-time burden of 5,960 hours (40 hours × 149 POs) at a cost of $693,386 (5,960 hr. × $116.34/hr).
- *Storage:* We estimate that a PACE organization will spend a total of $300 (2 × $150/each) for 2 four-drawer locking file cabinets. In aggregate, we estimate a one-time non-labor cost of $44,700 ($300 × 149 POs).
- *Update policies and procedures:* We estimate that PACE organizations will spend 10 hours at a cost of $729 (10 hours × $72.90/hr) for a compliance specialist to update and maintain related policies and procedures. In aggregate, we estimate a one-time burden of 1,490 hours (10 hours × 149 POs) at a cost of $108,621 (1,490 hr. × $72.90/hr).

The aggregate of this provision is a one-time impact of 13,410 hours (5960 hours (training materials) + 5960 hours (software development) + 1490 hours (policy updates) at a cost of $1,282,191 ($434,484 (Training materials) + $693,386 (software updates) + $44,700 (nonlabor purchase of storage) + $108,621 (policy updates).)

Since PACE organizations are already required to retain original communications related to a participant's care, health, or safety, and to make these communications accessible to CMS and the SAA upon request, this proposal does not impose any new information collection requirements for PACE organizations.

25. ICRs Regarding Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)

In this rule we are proposing to revise the Part D LIS income and resource standards at § 423.773 to expand eligibility for the full benefit to individuals who currently have the partial benefit and make a coordinating change in § 423.780. This proposal would change the level of assistance that an individual could qualify for in paying their Part D premiums, copays and deductibles. While there would be no change in the number of individuals eligible for the Part D LIS, it would create a transition of people from partial subsidy status to full benefit status.

The burden associated with determining eligibility for the Part D LIS is the time and effort for States or SSA to verify the income and resources and report eligibility to beneficiaries and CMS annually. Most individuals qualify for the Part D LIS because they qualify for Medicaid or other assistance in their State. The burden for States to determine and report eligibility is currently approved by OMB under control number 0938–0467 (CMS–R–74) at 54 respondents, 3,241 annual responses, a variable amount of time per response, and 1,082 estimated annual hours. We are not making any changes to any of the requirements or burden under the 0938–0467 control number.

C. Summary of Information Collection Requirements and Associated Burden Estimates

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11: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN*

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program		Enrollees	36,982	0.25	9246	28.01	258,980	258,980
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program		Pharmacists	36,722	0.0333	1223	120.86	147,812	147,812
423.2500 - 423.2536	Limited Income Newly Eligible Transition (LI NET) Program		LI NET sponsor	36,982	0.0333	1232	76.20	93,878	93,878
422.116	New Behavioral Specialty Types	0938-1346	MA Organizations	742	0.0833	62	76.20	4,724	
422.111 and 422.2267	MA Provider Termination Notices	0938-0753 (CMS-R-267)	MA Organizations	697	8	5,576	92.92	518,122	518,122
422.100 and 422.101	Posting New PA Guidance		MA Organizations	697	16	11,152	76.20	849,782	849,782
422.137	Utilization Management Review Committee	0938-0964	MA Organizations	697	1	697	76.20	159,334	159,334.
422.566 and 422.629	Medical Necessity Decisions		MA Organizations & Section 1876 Cost plans	65,126	-0.25	(16,282)	76.20	(1,240,688)	(1,240,688)

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
422.2261, 422.2264, 422.2265, 422.2267, 422.2274, 423.2261, 423.2264, 423.2267, and 423.2274	Marketing Provisions	0938-1051 (CMS-10260)	MA Organizations	697	3.25	2,265	76.20	172,593	172,593
423.4, 423.100, 423.120, and 423.128	Formulary Changes:Negative Change Request	0938-0964(CMS-10141)	Part D Parent Organizations	3,642	0.0833	303	120.86	36,621	36,621
423.4, 423.100, 423.120, and 423.128	Formulary Changes: Update in HPMS	0938-0964(CMS-10141)	Part D Parent Organizations	6,061	2	12,122	120.86	1,465,065	465,065
423.4, 423.100, 423.120, and 423.128	Formulary Changes: Update Website	0938-0964(CMS-10141)	Part D Parent Organizations	6,612	1	6,612	92.92	614,387	614,387
423.4, 423.100, 423.120, and 423.128	Formulary Changes: Enrollee Notifications	0938-0964(CMS-10141)	Part D Parent Organizations	65,535		65,535	0.59800	39,190	39,190
423.153d	MTM Eligibility: CMR Mailing cost	0938-1154	Part D Sponsors	4,124,502	0.6667	2,749,805	120.86	332,341,432	332,341,432
423.153d	MTM Eligibility: Safe disposal Mailing cost	0938-1154	Part D Sponsors	4,124,502			0.908	3,745,048	3,745,048
423.153d	MTM Eligibility: Writing CMRs	0938-1154	Part D Sponsors	2,360,564			0.015000	35,408	35,408

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
422.74	Involuntary Disenrollment: Loss of Special Needs Status	0938-0753	MA Organizations	55,127	0.117	6,450	76.20	491,490	491,490
422.74 (b)(2)	MSA Involuntary Disenrollment	0938-0753	MSA contracts	124	0.1	12	76.20	914	914
422.60 and 423.32	Reinstatement notices	0938-1378	MA Organizations and Part D Sponsors	225,906	0.017	3840	76.20	292,608	292,608
422.500, 422.513, 422.515, 423.501, 423.511, and 423.513	Final Settlement	0938-1054	MA Organizations	47	*Varies*	203	77.4	15,712	15,712
460.64	PACE Personnel Requirements	0938-0790 (CMS-R-244)	PACE Organizations	149	1	149	72.90	10,862	
460.64	PACE Personnel Requirements	0938-0790 (CMS-R-244)	PACE Organizations	149	5	745	104.9	78,151	
460.98	PACE Service Delivery Requests	0938-0790 (CMS-R-244)	PACE Organizations	149	1	149	72.90	10,862	
460.112	Notifying PACE Participants	0938-0790 (CMS-R-244)	PACE Organizations	149	4	596	72.90	43,448	
460.112	PACE Explanation of End of Life Options	0938-0790 (CMS-R-244)	PACE Organizations	10,927	1.1667	12749	76.75	978,486	978,486
460.112	PACE Explanation of End of Life Options	0938-0790 (CMS-R-244)	PACE Organizations	10,927	1	10,927	59.92	654,746	654,746
460.120	PACE Grievance Procedures	0938-0790 (CMS-R-244)	PACE Organizations	149	4	596	72.90	43,448	-
460.121	PACE Service Determination Process	0938-0790 (CMS-R-244)	PACE Organizations	2,188	-0.674	(1,475.0)	59.92	(88,382)	(88,382)
460.198	Participant Notification Requirement	0938-0790 (CMS-R-244)	PACE Organizations	2	1	2	72.90	146	146
460.200 and 460.210	Safeguarding data	0938-0790 (CMS-R-244)	PACE Organizations	149	40	5,960	72.90	434,484	

Regulation Section(s)	Item	OMB Control No.	Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
460.200 and 460.210	Safeguarding data: Software updates	0938-0790 (CMS-R-244)	PACE Organizations	149	40	5,960	116.34	693,386	
460.200 and 460.210	Safeguarding data: Storage	0938-0790 (CMS-R-244)	PACE Organizations	149			300.00	44,700	
460.200 and 460.210	Safeguarding data: Updating policies	0938-0790 (CMS-R-244)	PACE Organizations	149	10	1490	72.90	108,621	
Totals				*Varies*		2,899,295		343,055,370	341,064,562

*Blank cells in the "Total Cost Subsequent Years" column indicate $0 cost since the provision only has a first year cost. For two rows in the MTM provision blank cells in the "Burden per Response" and "Total Annual Burden" columns indicate "N/A" since the cost is non-labor.

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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 requirements. The 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 discussed above, please visit the CMS website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** section of this proposed rule and identify the rule (CMS–4201–P), the ICR's CFR citation, and OMB control number.

VIII. Regulatory Impact Analysis

A. Statement of Need

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) programs, and Programs of All-Inclusive Care for the Elderly (PACE). This proposed rule includes a number of new policies that would improve these programs for Contract Year 2024 as well as codify existing Part C and Part D sub-regulatory guidance.

The Parts C and D programs:

- The Bipartisan Budget Act (BBA) of 2018;
- The Consolidated Appropriations Act, 2021 (CAA);
- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act; and
- The Inflation Reduction Act of 2022 (IRA).

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)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This rule, under Executive Order 12866, is economically significant as it results in over $100 million in costs, benefits, or transfers annually. In accordance with the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs has designated this rule as a major rule as defined by 5 U.S.C. 804(2). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

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 2022, that threshold is approximately $165 million. This proposed rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of $165 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 PBMs). We expect that 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 $115.22 per hour, including fringe benefits, overhead, and other indirect costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 19 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore $2,200 (19 hours × $115.22). Therefore, we estimate that the maximum total cost of reviewing this proposed rule is $ 5.3 million ($2200 × 2,000 reviewers). However, we expect that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the rule will be reviewed by an individual reviewer; we therefore estimate the total cost of reviewing to be $ 0.5 million.

Note that this analysis assumes 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 proposed rule was reviewed by OMB.

C. Impact on Small Businesses—Regulatory Flexibility Analysis (RFA)

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.

A wide range of policies are being proposed in this rule. These policies codify, modify, and update current guidance governing MA organization bid requirements.

This rule has several affected stakeholders. They include: (1) MA organizations such as HMOs, local and regional PPOs, MSAs, PFFS and Part D sponsors; (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies; and (3) enrollees. Some descriptive data on these stakeholders are as follows:

- Pharmacies and Drug Stores, NAICS 446110, have a $30 million threshold for ''small size'' with 88 percent of pharmacies, those with under 20 employees, considered small.
- Direct Health and Medical Insurance Carriers, NAICS 524114, have a $41.5 million threshold for ''small size,'' with 75 percent of insurers having under 500 employees meeting the definition of small business. Several Medicare Advantage plans (about 30–40 percent) are not-for-profit resulting in a ''small entity'' status.
- Ambulatory Health Care Services, NAICS 621, including about 2 dozen subspecialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from $8 to $35 million (Dialysis Centers, NAICD 621492, have a $41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed $34 million.
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, Specialty Hospitals have a $41.5 million threshold for small size, with half of the hospitals (those with between 20–500 employees) considered small.
- Skilled Nursing Facilities (SNFs), NAICS 623110, have a $30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

We are certifying that this FC does not have a significant economic impact on a substantial number of small entities. To explain our position, we explain certain operational aspects of the Medicare program.

Each year, MA plans submit a bid for furnishing Part A and B benefits and the entire bid amount is paid by the government to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay basic premium, thus this percentage of plans is not ''significant'' as defined by the RFA and as justified in this section of this rule).

MA plans can also offer enhanced benefits, that is, benefits not covered under Original Medicare. These enhanced benefits are paid for through enrollee premiums, extra government payments or a combination. Under the statutory payment formula, if the bid submitted by a Medicare Advantage plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is. benefits not covered under Original Medicare) and or/lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

To the extent that the government's payments to plans for the bid plus the rebate exceeds costs in Original Medicare, those additional payments put upward pressure on the Part B premium which is paid by all Medicare beneficiaries, including those in Original Medicare who do not have the additional health services available in many MA plans.

Part D plans, including MA–PD plans,submit bids and those amounts are paid to plans through a combination Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries Part D plans receive special government payments to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by a variety of government fundingand in some cases by enrollee premiums. As a result, MA and Part D plans are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA regulations, such as those in this proposed rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either—(1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

If an MA plan bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees a premium for that amount. Historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. Since the number of plans bidding above the benchmark is 2 percent, this is not considered substantial for purposes of the RFA.

The preceding analysis shows that meeting the direct cost of this proposed rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

There are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government. However, the government additionally pays the plan a ''beneficiary rebate'' amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also partially be paid by enrollee premiums.) However, as noted previously, the number of plans bidding above the benchmark to whom this

burden applies do not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this rule would otherwise cause bids to increase, plans will reduce their profit margins, rather than substantially change their benefit package. This may be in part due to market forces; a plan lowering supplemental benefits even for 1 year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it can be advantageous to the plan to temporarily reduce profit margins, rather than reduce supplemental benefits.

We note that we do not have definitive data on this. Plans do not report to CMS the strategies behind their bids. More specifically, when supplemental benefits are reduced, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes. Notably, it may be inappropriate to consider the relevant regulatory impacts (and thus the profit considerations) as temporary because the issuance of a series of regulations sustains the effects.[227] As a result, changes in benefits packages may be plausible and we request comment on the assessment of this outcome in association with this proposed rule.

We next examine in detail each of the other stakeholders and explain how they can bear cost. Each of the following are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees for: (1) Pharmacies and Drug Stores, NAICS 446110; (2) Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) SNFs, NAICS 623110. Whether these providers are contracted or, in the case of PPOs and PFFS, not contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments. For non-contracted providers, § 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act require that a non-contracted provider accept payment that is at least what they would have been paid had the services been furnished in a fee-for-service setting. For contracted providers, § 422.520 requires that the payment is governed by a mutually agreed upon contract between the provider and the plan. CMS is prohibited from requiring MA plans to contract with a particular healthcare provider or to use a particular price structure for payment under the plan by section 1854(a)(6)(B)(iii) of the Act. Consequently, for these providers, there is no additional cost burden above the already existing burden in original Medicare.

Consequently, consistent with our conclusions stated earlier, the Secretary has certified that this proposed rule will not have a significant impact on a substantial number of small entities.

D. Anticipated Effects

Many provisions of this proposed rule have negligible impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact that cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when we estimated that provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or qualitative impact that cannot be quantified. The remaining provisions are estimated in section VIII 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 VIII. 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 experienced as a direct result of the statute. For further discussion of what is estimated in this Regulatory Impact Analysis, see Table 12 and the discussion afterwards.

1. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the LI NET Program (§ 423.2500 Through § 423.2536)

This proposal would implement section 118 of the CAA, which amends section 1860D–14 of the Act, to establish the Limited Income Newly Eligible Transition Program as a permanent part of Medicare Part D. This will ensure that the transitional drug coverage currently provided to low-income Medicare beneficiaries under the LI NET demonstration will continue indefinitely. Therefore, we anticipate this proposal will advance health equity by improving low income individuals' access to continuous, affordable health coverage, consistent with Executive Order 13985, issued January 20, 2021, on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. We also believe this proposal would improve the customer service experience of low-income beneficiaries consistent with the goals of the Executive Order 14058, Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government.

Using drug cost data from 2021, the CMS Office of the Actuary (OACT) projects the following program costs (in millions of dollars) over the next 10 years:

TABLE 13: PROJECTED LI NET PROGRAM DRUG COSTS ($ in MILLIONS)

	Fiscal Year									
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Costs	5	7	8	9	9	10	11	11	12	13

[227] Indeed, see similar discussion in previous regulatory impact analyses: *https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and* and *https://www.federalregister.gov/documents/2022/04/14/2022-07642/medicare-program-maximum-out-of-pocket-moop-limits-and-service-category-cost-sharing-standards.*

We note that OACT has provided cost/savings estimates each year under the LI NET demonstration, and they have not altered their methodology based on the program becoming permanent. Therefore, these projected costs are the same as what the government would have incurred if the demonstration continued. Further, the costs of the payments provided for under this program will continue, as they were under the demonstration, to be covered through the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance (SMI) Trust Fund.

2. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional With Expertise in the Field of Medicine Appropriate to the Requested Service (§§ 422.566 and 422.629)

The proposal that a physician or other health professional with expertise in the field of medicine appropriate to the requested service determine medical necessity is intended to provide a more meaningful clinical review informed by specific expertise. We believe this enhanced level of review will reduce unnecessary appeals, delays in treatment and the potential for adverse outcomes. The proposal requires obtaining the opinion of an appropriate expert at the organization determination level of review, which we believe will reduce denied organization determinations and, in turn, will reduce the number of cases getting into the appeals process.

While we can (and have) quantified the expected reduced appeals in the Collection of Information section, quantifying the costs of effects of delay in treatment and consequent possible adverse medical complications is not possible because we lack adequate data. For example, we lack data on the following: (1) currently how often do doctors without expertise determine medical necessity; (2) what percentage of these determinations are appealed and what percentage of these appeals are overturned; (3) of the overturned appeals what percentage of cases have medical complications specifically arising from delays; (4) of the upheld appeals what percentage have adverse medical complications directly attributable to the lack of original treatment; and (5) what is the average cost of these consequent adverse medical complications. In addition to requesting comment related to estimation of these listed effects, regarding the opportunity cost of medical experts' time when reallocated for the purpose of compliance with this provision, we welcome feedback related to whether this is a budget neutral reallocation, or whether a more detailed analysis would show added cost.

3. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

a. Standing Request for Translated Materials and Materials in Accessible Formats Using Auxiliary Aids and Services

We are proposing to specify in Medicare regulations that MA organizations, cost plans, and Part D sponsors must provide materials to enrollees on a *standing basis* in an accessible format using auxiliary aids and services or any non-English languages that is the primary language of at least 5 percent of the individuals in a plan benefit package service area upon receiving a request for the materials or otherwise learning of the enrollee's preferred language. The proposal would also extend to individualized plans of care for special needs plans.

Our proposed rule clarifies existing policy, therefore the impact to MA organizations, cost plans, and Part D plan sponsors depends on whether, and to what extent, they currently have processes in place to note an enrollee's language preference and need for auxiliary aids and services. As described in this section of this proposed rule, we believe many plans would not incur significant cost from the proposed requirement because plans currently comply with the proposal.

Enrollees who need translated materials or materials in an accessible format using auxiliary aids and services who are enrolled in MA, cost, or Part D plans that do not currently create a standing request for these materials would likely spend less time contacting their plan to request these materials as a result of this proposal. Any MA, cost, or Part D plan that has not created a standing request for enrollees requiring translated materials or materials in an accessible format using auxiliary aids and services would likely reduce their efforts to accept requests and resend the translated materials or materials in an accessible format using auxiliary aids and services.

CMS received information from Medicare-Medicaid Plans (MMPs) in Ohio and California about their requests for translated materials in 2021 and 2022. We include our assumptions from these discussions, but we are seeking comment on additional information that may better inform our estimates. Of the five MMPs in Ohio in 2021, only one of the plans accepted standing requests for translated materials or materials in an accessible format using auxiliary aids and services. A higher proportion (86 percent) of seven California MMPs that responded had established standing requests due to State oversight ensuring California MMPs followed the State-specific marketing guidance; however, we believe the Ohio MMPs landscape betters represents MA organizations as a whole. Therefore, we estimate that 20 percent or 171 [228] MA organization, cost plan, and Part D plan sponsor contracts are currently accepting standing requests and would not be impacted by this proposal. Therefore, an estimated 80 percent or 683 MA organization, cost plan, and Part D plan sponsor contracts would need to implement this proposed requirement. We believe our analysis of MMP plans, which cover Part C and Part D benefits, also applies to MA organization, cost plan, and Part D plan sponsors. We request comment on whether MA organization, cost plan, and Part D plan sponsors accept standing requests for translated materials or materials in an accessible format using auxiliary aids and services at a greater or lesser extent than MMPs.

Based on the information we received from MMPs, we are uncertain if establishing a standing request for translated material or materials in an accessible format using auxiliary aids and services will increase or decrease administrative cost for the estimated 683 MA organization, cost plan, and Part D plan sponsor contracts impacted by our proposal. Based on information from MMPs who have implemented a standing request, we believe establishing a process for standing requests would require about 200 hours of business operations specialist [229] time during the first year or 136,600 hours (200 hr * 683 MA, cost, and Part D contracts) at a cost of $10,408,920 (136,600 hr × $76.20/hr wage for a business operations specialist).

We assume that this initial cost would be offset by a reduction cost for MA organizations, cost plans, and Part D plan sponsors to resend materials in the correct translated or accessible format. We also expect that implementing a standing request process would reduce

[228] Based on 854 MA, cost, and Part D plan sponsor contracts in the May 2022 Monthly Contract and Enrollment Summary Report. Retrieved from *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2022-05.*

[229] Based on the BLS wage information for business operations specialist (code 13–1199) whose wage we estimate at $76.20 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*).

future costs to MA organizations, cost plans, and Part D sponsors by decreasing rework of sending two sets of information, one in the incorrect language or format and the other in the correct format. However, establishing a standing request for translated material or materials in an accessible format using auxiliary aids and services as proposed could result in more enrollees requesting to consistently receive these materials at an additional cost to MA organizations, cost plans, and Part D plan sponsors. We request comment on our assumptions and the potential savings or costs to MA organizations, cost plans, and Part D plan sponsors.

b. Require FIDE SNPs and HIDE SNPs and Applicable Integrated Plans To Translate Materials Into the Medicare Translation Standard Plus Additional Medicaid Languages

We are proposing to require that FIDE SNPs, HIDE SNPs and AIPs translate materials into any languages required by the Medicare translation standard plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts.

Our proposed rule slightly modifies existing policy, so the impact to FIDE SNPs, HIDE SNPs, and AIPs depends upon whether, and to what extent, these plans are already translating materials in ways that would meet our proposed requirements. We note that translation requirements vary by State. Therefore, we expect no impact in States where the applicable Medicaid and Medicaid translation requirements result in the same outcome. We expect marginal impacts where State requirements result in translation into languages not required by the current MA rules at §§ 422.2267(a)(2) and 423.2267(a)(2). However, even in these States, FIDE SNPs, HIDE SNPs, AIPs (in combination with their affiliated Medicaid managed care plans) have translators on staff or access them via contractors because of existing translation requirements.

For contract year 2022, MA organizations sponsor 292 FIDE SNPs, HIDE SNPs, and AIPs. We expect that some portion of these FIDE SNPs, HIDE SNPs, and AIPs already translate their Medicare materials in ways that meet our proposed requirement, but we do not have good estimate of how many. While HPMS identifies the Medicare translation requirements for each MA and Part D plan sponsor at the plan level, we do not have a good source of the State-specific Medicaid translation requirements since they differ by State and there is no one source of information outlining these requirements. For purposes of this analysis, we estimate that 75 percent of the FIDE SNPs, HIDE SNPs, and AIPs currently translate their Medicare materials in ways that would meet our proposed requirement and 25 percent or 73 of these FIDE SNPs, HIDE SNPs, and AIPs do not.

Section 422.2267(e) requires MA plans to provide 29 materials to current and prospective MA plan enrollees, as applicable and § 423.2267(e) requires Part D sponsors to provide an additional 18 materials to current and prospective enrollees for a total of 47 materials. We estimate that the proposed provision would require 73 FIDE SNPs, HIDE SNPs, and AIPs to translate 47 materials into one additional language. On average, we expect these plans to translate materials into one additional language based on our experience with MMPs where, out of nine states, only two states (California and Rhode Island) required translation of materials into additional languages beyond the Medicare translation standard. California required MMPs to translate materials into nine additional languages in certain counties and Rhode Island required MMPs to translate materials into two additional languages. Collectively, these 47 materials include an estimated 253,311 words.[230] At a cost of $56.16/hr,[231] we estimate a translator could translate 500 words/hr.[232] The aggregate cost is $2,076,988, which is the product of the following:

- 253,311 words for one set of 47 materials.
- 500 words translated per hour.
- 73 FIDE SNPs.
- $56.16/hr wage.

Translating one set of 47 materials into one other language would cost an estimated $28,452 (253,311 words/500 words/hr x $28.08/hr x 2 for (100 percent for fringe benefits)). Based on these assumptions, it would cost $2,076,996 for 73 FIDE SNPs, HIDE SNPs, and AIPs to translate one set of materials into one other language. Any additional documents needing translation would be a one-time cost with a smaller cost to update the documents in future contract years.

4. Part D Medication Therapy Management (MTM) Program Targeting Requirements (§ 423.153)

We are proposing to revise § 423.153(d)(2) to: (1) codify the current 9 core chronic diseases in regulation, and add HIV/AIDS to the list of core chronic diseases for a total of 10 core chronic diseases and require Part D sponsors to include all core chronic diseases in their MTM targeting criteria; (2) lower the maximum number of Part D drugs a Part D sponsor may require from 8 to 5 drugs and require sponsors to include all Part D maintenance drugs in their targeting criteria; and (3) change the annual cost threshold methodology to be commensurate with the average annual cost of 5 generic drugs ($1,004 in 2020). We estimate that these proposals would increase the number of Part D beneficiaries eligible for MTM services.

These proposed changes would allow us to address specific problems identified in the Part D MTM program by improving access to MTM services for enrollees with multiple chronic conditions who are taking multiple Part D drugs, reducing marked variability in MTM eligibility across plans, better aligning with Congressional intent to improve medication use and reduce the risk of adverse events by focusing more on case complexity and drug regimen, and establishing a more reasonable cost threshold that would keep the MTM program size manageable. Almost all of the chronic diseases that CMS is proposing to codify as core chronic diseases are more prevalent among underserved populations, including minority and lower income populations. As a result, we anticipate that our proposed changes will increase eligibility rates among those populations, promoting consistent, equitable, and expanded access to MTM services.

We estimate that these proposals would increase the number and percentage of Part D enrollees eligible for MTM services from 4.5 million (9 percent) to 11.4 million (23 percent). Although the increase in MTM program enrollment is estimated to cost $336,121,888 for the provision of required MTM services, we cannot definitively score this proposal because there may be other administrative costs attributable to MTM, and MTM program costs are not a specific line item that can

[230] Extrapolated based on data from CMS–4144–F (76 CFR 21549) that estimated 91,623 words for translation of approximately 17 plan materials.

[231] Mean hourly wage for interpreters and translators, May 2021 retrieved from: *https://www.bls.gov/oes/current/oes273091.htm* The mean rate of $28.08 was doubled to include fringe benefits and overwork time.

[232] Translation rates vary widely and also depend on the technical nature of what is translated as well as whether adequate review time is included. The consensus of multiple websoures i) *https://www.proz.com/forum/money_matters/300163-words_per_hour.html* ii) *https://www.pactranz.com/translation-times/* iii) *https://www.getblend.com/blog/output-words-per-day/* iv) *https://www.trainingfortranslators.com/2011/01/20/webinar-question-how-many-words-per-day/* provides ranges from 200 words/hour to 1000 words per hour. We have selected 500 as a reasonable average and invite stakeholder feedback on the reasonableness of this assumption.

be easily extracted from the bid. Additionally, published studies have found that MTM services may generate overall medical savings, for example, through reduced adverse outcomes including reduced hospitalizations and readmissions, outpatient encounters, or nursing home admissions.[233] CMS is unable to generate reliable savings estimates from the published studies due to limitations in potential study design, including the lack of a control group and numerous intervening variables. The burden associated with these proposed changes is addressed in the Collection of Information section (section VII.) of this proposed rule in the ICR section for MTM targeting criteria.

5. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 401.305(a)(2), 422.326(c), and 423.360(c))

The proposed regulatory provisions would amend the existing regulations at §§ 401.305(a)(2), 422.326(c), and 423.360(c) to change the standard for an ''identified overpayment'' for Medicare Parts A, B, C, and D by adopting and codifying, by reference, the knowledge standard set forth in the False Claims Act at 31 U.S.C. 3729(b)(1). The regulations implementing section 1128J(d) (C/D final overpayment rule 79 FR 29844 (May 23, 2014) §§ 422.326 and 423.360, and A/B final overpayment rule 81 FR 7654 (February 12, 2016), §§ 401.301, 401.303 and 401.305) proposed only technical changes for overpayment reporting.

We now propose to amend the final Parts A & B Overpayment Rule at § 401.305(a)(2) to remove the reference to ''reasonable diligence'' and replace it with language at section 1128J(d)(4)(A) of the Act that gives the terms ''knowing'' and ''knowingly'' the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). We do not have a basis for estimating the impact associated with this amendment. We solicit comment on the analysis and conclusions provided in the RIA.

The provision at § 422.326(c) was vacated by the United States District Court for the District of Columbia in 2018, and the District Court noted in its decision that ''(t)he False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. 1320a-7k(d)(3)—imposes liability for erroneous ('false') claims for payment submitted to the government that are submitted 'knowingly . . . a term of art defined in the FCA to include false information about which a person 'has actual knowledge,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' '' *Id.* at 190. This proposed rule proposes to codify this knowledge standard.

Since we now propose to amend the final Parts C & D Overpayment Rule at §§ 422.326(c) and 423.360(c), to remove the reference to ''reasonable diligence'' and replace it with language at section 1128J(d)(4)(A) that gives the terms ''knowing'' and ''knowingly'' the same meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A), we do not have a basis for estimating the impact associated with this amendment. We solicit comment on the analysis and conclusions provided in the RIA.

6. Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74)

This rule requires involuntary disenrollment for individuals enrolled in an MA MSA plan. The requirement proposed at §§ 422.74(b)(2)(vi) and (d)(10) would establish a process for involuntary disenrollment for an individual who loses eligibility mid-year and, more specifically, the requirement for the MA organization to give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual for disenrollment for any of the reasons other than death or loss of entitlement to Part A or Part B, or unlawful presence in the United States.

This disenrollment triggers three events:

- CMS will no longer make prospective monthly payments to the MSA plan for this individual.
- Per § 422.314(c), CMS will recover the remainder of the lump-sum deposited into the MSA enrollee's account. MSA enrollees receive a lump-sum deposited at the beginning of the calendar year or on the first month coverage begins in the plan (if the enrollee is entitled to Medicare in the middle of the year and he/she joins a Medicare MSA plan at that time). The funds deposited in the Medical Savings Account for health care expenses can be used to pay for the enrollee's health care before the high deductible is reached.

If an MSA enrollee is disenrolled, mid-year, for the first of the month after no longer meeting the MSA eligibility criteria, CMS will recover the remaining whole months from the disenrolled beneficiary by offsetting any amount Medicare pays the plan for new enrollees in a month.

- Involuntarily disenrolled individuals would be defaulted to enrollment in Original Medicare, as proposed in § 422.74(e)(1), which will now pay claims incurred by the former MSA enrollee. The former MSA enrollee also has the option to elect to join another MA plan during a valid enrollment period.

To analyze these three effects, we note that the sum of the risk adjusted capitated payment and the contribution of the lump sum payment amount to the individual's medical savings account should equal the benchmark for payment by Medicare for MA coverage of a beneficiary. In other words, the three effects are largely cancelled out resulting in an insignificant impact to the Medicare Trust Funds. MA costs and FFS costs are somewhat different due to differences in between the two programs regarding provider contracting and coding intensity, as well as pricing for margin and profits. However, because the number of individuals who are involuntarily disenrolled from MA MSA plans is expected to be very small, the overall impact to the Medicare Trust Funds is insignificant.

7. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

We are proposing to add, remove, and update certain measures and to make methodological clarifications (to codify current practice and policies) to the Part C and D Star Ratings program. These measure additions, removals, and updates and methodological clarifications are routine, and routine changes have historically had very little or no impact on the highest ratings (that is, overall rating for MA–PD contracts, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). Hence, we anticipate there will be no, or negligible, impact on the Medicare Trust Fund from these routine changes we are proposing in this rule. Beyond the Trust Fund, there may be effects on supplemental benefits, premiums, and plan profits. These impacts will likely vary significantly from plan to plan (or contract to contract) based on the business strategies and the competitive landscape for each plan and contract.

We are also proposing some methodological enhancements to the Star Ratings as follows: replacing the current reward factor with an HEI reward, reducing the weight of patient experience/complaints and access measures, removing guardrails,

[233] Ramalho de Olivera, D; Brummel, A; Miller, D. Medication Therapy Management: 10 Years of Experience in a Large Integrated Health Care System J Manag Care Pharm. 2010;16(3):185–95.

modifying the hold harmless policy used for the improvement measures, adding a rule for the sub-regulatory removal of Star Ratings measures when a measure steward other than CMS retires the measure, and removing the 60 percent rule that is applied when adjusting Star Ratings for extreme and uncontrollable circumstances (for example, natural disasters like hurricanes or public health emergencies). We anticipate that removing guardrails, removing the 60 percent rule, and adding a rule for subregulatory measure removal would each have a negligible impact on the highest ratings. Three of our proposed enhancements have the potential to cause a contract's Star Rating to change: (1) applying the improvement measure highest rating hold harmless provision only to 5 star contracts instead of for those contracts with a rating of 4 or higher stars; (2) decreasing the weight of patient experience, complaints, and access measures from four to two; and (3) replacing the current reward factor with an HEI that would reward contracts for doing well serving enrollees with various social risk factors.

We simulated the cumulative impact of the proposed changes on MA–PD contracts by contract size using the 2021 Star Ratings. Consistent with what we have observed historically, there is more enrollment in high performing contracts as seen in Table 14. All enrollment categories see a small decrease in the average overall rating ranging from –0.06 to –0.15 under this simulation. The amount of the decrease in the overall rating increases as the enrollment size categories increase, with the proposed changes having a somewhat larger impact for higher rated contracts.

TABLE 14: OVERALL RATING SIMULATIONS BY CONTRACT SIZE

Enrollment Category	Number of Contracts	2021 Overall Rating Average	Simulated Overall Rating Average	Difference
< 5,000	76	3.54	3.48	-0.06
>= 5,000 - < 25,000	137	3.69	3.62	-0.07
>= 25,000 - < 100,000	125	3.94	3.84	-0.10
>= 100,000	55	4.13	3.97	-0.15

We also simulated the cumulative impact of the proposed changes to the overall rating by geographical area—specifically, by State, DC, and Puerto Rico. Since the service area of a contract can include multiple states, we assigned to each enrollee the rating of their MA contract and calculated the average rating across all enrollees residing in each State. The average change in the overall rating is a decrease of 0.17, with the changes ranging from 0.0 to –0.37 across geographic areas. Table 15 shows the simulated changes by State, DC, and Puerto Rico. The second column is the number of MA enrollees in each State in contracts that received the 2021 overall rating. In most cases, but not all, there are larger declines in areas that had on average higher 2021 overall ratings.

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TABLE 15: STAR RATINGS SIMULATIONS BY STATE, DC AND PUERTO RICO

State	Number of Enrollees	2021 Overall Rating	Simulated Overall Rating	Difference
AK	1,524	4.08	3.94	-0.14
AL	443,969	4.24	3.96	-0.28
AR	170,915	3.59	3.44	-0.15
AZ	521,901	3.76	3.71	-0.05
CA	2,657,281	4.46	4.43	-0.02
CO	367,021	4.30	4.10	-0.21
CT	271,820	4.07	3.96	-0.10
DC	19,146	4.32	4.13	-0.18
DE	34,468	3.95	3.86	-0.09
FL	2,111,559	4.11	3.95	-0.16
GA	697,263	3.92	3.77	-0.15
HI	127,315	4.05	3.74	-0.31
IA	131,963	3.97	3.85	-0.13
ID	113,540	3.80	3.72	-0.08
IL	548,385	4.11	3.87	-0.24
IN	402,282	3.98	3.74	-0.23
KS	97,754	3.85	3.69	-0.15
KY	313,488	3.90	3.65	-0.25
LA	339,228	4.24	3.98	-0.26
MA	309,105	4.55	4.18	-0.37
MD	127,039	4.28	4.00	-0.28
ME	119,565	4.43	4.10	-0.33
MI	819,565	3.76	3.69	-0.08
MN	458,194	4.31	3.95	-0.36
MO	445,550	4.12	3.84	-0.28
MS	123,683	3.70	3.49	-0.21
MT	44,284	4.00	3.93	-0.07
NC	746,214	4.13	3.96	-0.17
ND	23,931	4.02	3.92	-0.10
NE	56,025	4.13	3.90	-0.23
NH	55,680	3.98	3.74	-0.23
NJ	484,539	3.87	3.83	-0.05
NM	153,762	3.73	3.63	-0.09
NV	199,573	3.92	3.87	-0.05
NY	1,510,549	3.82	3.72	-0.10
OH	943,397	3.98	3.90	-0.08
OK	149,407	3.75	3.63	-0.12
OR	391,460	4.13	3.89	-0.25
PA	1,157,687	4.10	3.98	-0.12
PR	592,702	4.03	4.03	0.00
RI	84,615	4.02	3.87	-0.15
SC	310,810	3.73	3.57	-0.16
SD	37,222	3.99	3.85	-0.13
TN	548,221	4.11	4.01	-0.10

State	Number of Enrollees	2021 Overall Rating	Simulated Overall Rating	Difference
TX	1,638,848	3.95	3.79	-0.17
UT	148,224	3.95	3.65	-0.30
VA	335,867	3.91	3.80	-0.11
VT	17,644	3.86	3.57	-0.28
WA	450,597	4.05	3.80	-0.24
WI	488,875	4.14	3.94	-0.20
WV	133,231	3.90	3.61	-0.29
WY	4,101	3.60	3.49	-0.11

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We calculated the cost impacts summarized in Tables 12 and 13 due to these proposed Star Ratings updates by quantifying the difference in the MA organization's final Star Rating with the proposed changes and without the proposed changes. We assume Medicare Trust Fund impacts due to the Star Ratings changes associated with these three proposed revisions to the methodology. The first two of these changes would be effective for the 2026 Star Ratings and would impact the 2027 plan payments and 2027 Quality Bonus Payments. The introduction of the HEI reward in lieu of the current reward factor would impact the 2027 Star Ratings and would impact the 2028 plan payments and 2028 Quality Bonus Payments.

All impacts are considered transfers, but we request comment on the extent to which provision of goods or services would increase or decrease in association with the payment changes. 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:

- A Star Rating of 4.0 or higher will result in a QBP for the MA contract, which, in turn, leads to a higher benchmark for the MA plans offered by the MA organization under that contract. 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).
- 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 Private Health Baseline assumptions are updated with the assumed Star Ratings changes described in this proposed rule. We first estimated the three proposed changes to the Star Ratings calculations as independent of each other and, since there are likely overall Star Rating interactions between the three changes, the impacts, as shown in Table 16, should be viewed separately and should not be summed. The negative values in this section of this proposed rule represent net savings to the Medicare Trust Funds. For the improvement measure hold harmless provision, net savings are estimated to be between $2.08 billion in 2027 and $3.52 billion in 2033, resulting in a ten year savings estimate of $19.53 billion, which equates to 0.3 percent of the Private Health Baseline for the years 2024 through 2033. The patient experience/complaints and access measure weight provision is expected to result in net savings of between $330 million in 2027 and $580 million in 2033, resulting in a 10 year savings estimate of $3.28 billion. This amount equates to 0.05 percent of the Private Health Baseline for 2024–2033. The replacement of the current reward factor with the HEI reward is expected to result in net savings of between $670 million in 2028 and $1,050 million in 2033 resulting in a 10-year savings estimate of $5.12 billion. $5.12 billion represents 0.08 percent of the Private Health Baseline for the years 2024–2033. These projections are based on simulations using data from the 2020 and 2021 Star Ratings.

TABLE 16: NEW IMPACTS OF STAR RATINGS PROPOSED PROVISIONS (NET IMPACTS ($ Millions) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES)

Calendar Year	Improvement Measure Hold Harmless	Percent of Private Health Baseline	Patient Experience/Complaints/Access Measure Weight	Percent of Private Health Baseline	Health Equity Index Reward	Percent of Private Health Baseline
2024	-	0.00%	-	0.00%	-	0.00%
2025	-	0.00%	-	0.00%	-	0.00%
2026	-	0.00%	-	0.00%	-	0.00%
2027	(2,080)	-0.36%	(330)	-0.06%	-	0.00%
2028	(2,330)	-0.37%	(380)	-0.06%	(670)	-0.11%
2029	(2,550)	-0.37%	(430)	-0.06%	(750)	-0.11%
2030	(2,760)	-0.38%	(480)	-0.07%	(820)	-0.11%
2031	(2,980)	-0.38%	(530)	-0.07%	(880)	-0.11%
2032	(3,310)	-0.38%	(550)	-0.06%	(950)	-0.11%
2033	(3,520)	-0.38%	(580)	-0.06%	(1,050)	-0.11%
Total	(19,530)	-0.29%	(3,280)	-0.05%	(5,120)	-0.08%

We also estimated the cumulative impact of the proposed changes to the Star Ratings calculations since there are interactions between the changes. The impacts are showing in Table 17. The negative values represent net savings to the Medicare Trust Funds. For the Star Ratings updates, net savings are estimated to be between $2.41 billion in 2027 and $4.57 billion in 2033, resulting in a 10-year savings estimate of $ 24.97 billion, which equates to 0.37 percent of the Private Health Baseline for the years 2024 through 2033.

TABLE 17: NET IMPACTS ($ Millions) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Net Impact Star Ratings Updates	Percent of Private Health Baseline
2024	-	0.00%
2025	-	0.00%
2026	-	0.00%
2027	(2,410)	-0.42%
2028	(2,980)	-0.47%
2029	(3,280)	-0.48%
2030	(3,560)	-0.48%
2031	(3,860)	-0.49%
2032	(4,310)	-0.49%
2033	(4,570)	-0.49%
Total	(24,970)	-0.37%

8. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)

In this rule we are proposing to revise the Part D LIS income and resource standards at § 423.773 to expand eligibility for the full benefit to individuals who currently have the partial benefit and make a coordinating change in § 423.780. This proposal would change the level of assistance that an individual could qualify for in paying their Part D premiums, copays and deductibles. While there would be no change in the number of individuals

eligible for the Part D LIS, it would create a transition of people from partial subsidy status to full benefit status.

The result of this change is the Federal Government providing more subsidies to low income Medicare beneficiaries for Part D coverage which would result in additional costs to the Medicare Trust Fund. The following table reflects the scored government costs for expanding the full LIS subsidy to the current partially-subsidized LIS beneficiaries starting January 1, 2024. Included in this table are the breakdown of increases for both the low income cost-sharing subsidy (LICS) and the low income premium subsidy (LIPS). OACT arrived at the cost estimate by assuming that the ratio of post-LICS-out-of-pocket as a percentage to the total drug cost for the partial subsidy beneficiaries would be similar to that of the full subsidy beneficiaries. In other words, (plan benefits + LICS)/total drug cost for the partial subsidy beneficiaries will be the same as that for the full subsidy beneficiaries.

TABLE 18: PROJECTED COSTS FOR EXPANDING LOW INCOME SUBSIDIES

	Calendar Year Incurred ($ in millions)									
	2024	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**
LIS total	$169	$180	$193	$207	$221	$237	$253	$269	$286	$304
LICS	$135	$144	$155	$166	$178	$191	$205	$218	$232	$247
LIPS	$34	$36	$38	$41	$43	$46	$48	$51	$54	$57

E. Alternatives Considered

In this section, CMS includes discussions of Alternatives Considered for several provisions. Several provisions of this proposed rule reflect a codification of existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification of this existing policy would not affect compliance. In such cases, the preamble typically discusses the effectiveness metrics of these provisions for public health. Also, in these cases,, different enforcement methods and different levels of stringency, are not fully relevant since the provision is already being complied with adequately. Alternative analysis is not provided for these provisions.

1. Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors That Are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§ 422.500(b), 423.501, 422.528, 423.521, 422.529, and 423.522)

As an alternative to our proposal to require MA organizations and Part D sponsors respond to CMS with a summary of their agreement or disagreement with the final settlement amount, we considered two others approaches.

First, we considered requiring a response by all contracts, regardless of whether or not they disagreed with CMS's calculation of the final settlement amount. This would result in an aggregate burden of $26,931.

Second, we considered requiring MA organizations and Part D sponsors that are consolidating, non-renewing, or terminating their contract to internally calculate the final settlement amount, have a financial officer attest that the final settlement amount meets actuarial standards, and report to CMS the results within a specified timeframe. For purposes of this alternative, we are using the same assumption detailed in the ICR regarding final settlement. We would add the burden of attestation which is the burden of a chief executive and manager taking 1 hour each for the purposes of meeting to describe the final settlement amount and attest to the accuracy of the calculation. As indicated in section VII.B.16. of this proposed rule historically, on average, from the period 2015 through 2020, 44 contracts agreed with the CMS decision on final settlement amount and 3 requested a review.

The revised increased burden would be $1,018 (3 contracts * 2 hours for attestation * $169.67).

For comparisons we list these two approaches and the approach, we adopted in VII.C.14. of this proposed rule.

- *Finalized approach*: Total burden of $15,712.
- *Alternate approach where every contract writes a summary: $26,931.*
- *An addendum of attestation to either of the above 2 approaches: An additional $1,018.*

Further information is provided in Table 19 in this section of this rule.

TABLE 19: TOTAL STAFF BURDEN (hr) FOR CALCULATING FINAL SETTLEMENT

Occupation	Burden per Entity for Required Tasks (in hours)	Wage/hr ($)	Total burden per entity ($)
Managers	1	134.52	134.52
Chief Executive	1	204.82	204.82
Total	2	169.67	339.34

We are not proposing the first alternative because we do not believe that adding a requirement to our current process for MA organizations and Part D sponsors to acknowledge receipt of the notice of final determination and indicate they agree with the final determination amount is beneficial. CMS believes this will not enhance our process by providing CMS information on whether an MA organization or Part D sponsor agrees with the final settlement and instead propose that MA organizations and Part D sponsors request a review of the CMS calculated final settlement amount if they disagree.

We are not proposing the second alternative because we believe that requiring MA organizations and Part D sponsors to calculate the final settlement amount would introduce a significant financial and administrative burden on MA organizations and Part D sponsors that are consolidating, non-renewing, or terminating without improving on the efficiency of our proposed process.

2. Part D Medication Therapy Management (MTM) Program Targeting Criteria (§ 423.153)

We considered two alternatives to our proposal. The first alternative we considered would maintain our proposed changes related to chronic diseases and Part D drug utilization, but would establish a cost threshold commensurate with the average annual cost of 2 Part D maintenance drugs. Under this alternative, CMS would calculate the dollar amount based on the average daily cost of both brand and generic drugs identified as maintenance drugs in Medi-Span. Based on 2020 PDE data, the cost threshold under this alternative would be $1,657, with an estimated program size of about 9,363,087 beneficiaries (19.53 percent of the total Part D population) and an estimated increased burden of $251,600,394.

The second alternative we considered would include our proposed changes related to chronic diseases, retain the current maximum number of Part D drugs a sponsor may require for MTM program enrollment at 8 drugs, require sponsors to include all Part D maintenance drugs in their targeting criteria, and establish a cost threshold commensurate with the average annual cost of 5 generic maintenance drugs. Under this alternative, CMS would calculate the dollar amount of the cost threshold as proposed but would only include generic maintenance drugs. Based on 2020 PDE data, the cost threshold under this alternative would be $840, with an estimated program size of 7,924,203 beneficiaries (16.53 percent of the total Part D population) and an estimated increased burden of $177,022,820.

We are not proposing the first alternative primarily because a cost threshold at $1,657 would continue to exclude too many Part D enrollees who meet the other targeting criteria. Based on 2020 data, between 25 and 50 percent of the Part D enrollees who have 3 or more core chronic diseases and are taking 5 or more Part D maintenance drugs would be ineligible because their annual Part D covered drug cost may not meet or exceed this cost threshold amount (25th percentile is $823; median is $2,778); therefore, many eligibility gaps based on Part D drug spend would persist. We also have concerns that including brand drugs in the cost threshold calculation could potentially contribute to greater volatility in the dollar amount each year.

We are not proposing the second alternative because, as discussed in section III.R. of this proposed rule, we want to reduce MTM eligibility gaps to ensure that more individuals who would most benefit from MTM services have access. Individuals taking 5 or more prescription drugs are associated with a higher risk of potentially inappropriate medication use.[234] Thus, we believe it is appropriate to reduce the maximum number of Part D drugs a sponsor may require for MTM program enrollment to 5 drugs, as reflected in our proposed changes.

Overall, we believe our proposed changes represent the best way to address unmet beneficiary needs while balancing program size and burden on Part D sponsors.

3. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.100, 422.101, 422.112, 422.137, 422.138)

Both the reasons for proposing the UM Committee requirement provisions and the alternatives they are intended to counteract are discussed in the respective preambles. Because we cannot quantify any of these we have not included a repetition of this analysis in the RIA. A brief summary is as follows:

- The proposed regulation clarifies coverage criteria of basic benefits standards by requiring MA plans to make medical necessity determinations based on Traditional Medicare coverage and benefit criteria as reflected in Medicare statutes and regulations, NCDs and LCDs and prohibiting the use of internal coverage criteria or additional medical necessity standards except in limited situations. This is major policy shift in which MA plans may only deny coverage for Medicare items and services based on Traditional Medicare coverage rules. We understand that this provision will create new burden which is difficult to quantify.
- The proposed regulation also requires plans to follow a specific process in developing internal coverage policies and to provide a public summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations. We provided an impact analysis in section VII.C.4 of this proposed rule of one quantifiable aspect of this proposal. We will also solicit stakeholder input on aspects of the proposal and its impact.
- The regulation requires a PA approval to be valid for the duration of the approved course of treatment. In combination with the proposals to limit when MA plans may deny coverage (or use internal coverage criteria that are not used in Traditional Medicare), this will limit an MA organization's ability to approve only part of what a provider has ordered or prescribed. In addition, the proposal would minimize repetitive PA requirements for enrollees on an appropriate, chronic, stable therapy. It would be qualitatively beneficial for the enrollee.
- The proposed regulation establishes a minimum 90-day transition period when an enrollee switches to a new plan, or switches from FFS to an MA plan (including new MA plan members who are also new to Medicare as well) for any ongoing courses of treatment so that treatment is not interrupted while UM requirements are addressed. This was adopted from similar transition periods in Part D; we believe it is appropriate to align the transition period and scope with the current transition requirements in Part D. This proposal is qualitatively beneficial for the enrollee.
- The proposed regulation requires MA organizations to establish a committee (similar to a P&T committee), led by the Medical Director, that reviews utilization management policies annually and keeps current of Medicare statutes and regulations, LCDs and NCDs. It also includes a discussion of

[234] M.-C. Weng, et al., The impact of number of drugs prescribed on the risk of potentially inappropriate medication among outpatient older adults with chronic diseases, QJM: An International Journal of Medicine, Volume 106, Issue 11, November 2013, Pages 1009–1015, *https://doi.org/10.1093/qjmed/hct141.*

''gold-carding'' in the preamble that encourages MA plans to implement gold-carding programs to improve efficiency and reduce burden on providers with a proven track record of compliance. This is qualitatively beneficial for the enrollee. It was modeled on similar committees used for Part B step therapy programs and by Part D plans. Its major effect is to ask plans to review their policies.

We re-emphasize that we are not able to fully quantify all of these and the discussion of reasons is discussed in the preamble.

4. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

As an alternative to our proposal to have a tiered health equity index reward, we have considered a non-tiered approach. We have proposed a tiered HEI reward structure based on the percentage of enrollees in each contract who have the specified SRFs. We propose that contracts that have percentages of enrollees with any of the specified SRFs in a given year that are greater than or equal to one-half of the contract-level median percentage of enrollees with the specified SRFs up to, but not including, the contract-level median would qualify for one-half of the HEI reward. Contracts that have percentages of enrollees with any of the specified SRFs greater than or equal to the contract-level median would qualify for the full HEI reward.

We have also considered and are soliciting comment on an alternative non-tiered HEI reward structure, where all contracts with percentages of enrollees with any of the specified SRF greater than or equal to one-half of the contract-level median would qualify for the full HEI reward. Both the tiered and non-tiered HEI reward structures align with our goals of promoting enrollment of enrollees with SRFs and not rewarding contracts that may do well among enrollees with SRFs but serve very few enrollees in this population, although the tiered HEI reward structure goes further in aligning with these goals. The non-tiered HEI reward structure aligns better with the goal of ease of use and understanding for contracts and other stakeholders. Although the non-tiered approach would slightly increase the mean HEI reward, it does not impact the number of contracts qualifying for the reward.

F. Accounting Statement and Table

The following Table 20 summarizes 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 20, we have prepared an accounting statement showing the costs and transfers associated with the provisions of this final rule for calendar years 2024 through 2033. Table 20 is based on Table 21 which lists transfers and costs by provision and year. Table 20 is expressed in millions of dollars with costs listed as positive numbers and transfers of savings (reduction in dollar spending) to the Medicare Trust Fund listed as a savings. As can be seen, the net annualized cost of this rule is about $580 million per year. This cost is offset by a reduction in dollar spending (savings) to the Medicare Trust Fund of about $2 billion per year. Minor seeming discrepancies in totals in Tables 21 reflects use of underlying spreadsheets, rather than intermediate rounded amounts. A breakdown of these costs of this proposed rule by provision may be found in Table 21.

TABLE 20: ACCOUNTING TABLE (MILLIONS $)*

Item	Annualized at 7%	Annualized at 3%	Period	Who is Impacted
Net Annualized Monetized Cost in 2023 dollars	575.4	580.0	2024-2033	Federal Government, MA organizations, and Part D sponsors
Transfers to the Medicare Trust Fund	(2,175.5)	(2,356.8)	2024-2033	From MA plans and Part D Sponsors to the Medicare Trust Fund

* Cost is expressed as a positive number. The savings (reductions in dollar spending) to the Medicare Trust Fund is expressed as a negative Note: These estimates reflect a non doubling of wages to account for fringe benefits for enrollees. Had we doubled wages for enrollees then the annualized impact at 7% (and 3%) would be 575.6 and 580.2 respectively rather than 575.4 and 580.0.

The following Table 21 summarizes costs, and transfers by provision and year and forms a basis for the accounting Table 20. In Table 21, costs are expressed as positive numbers while savings to the Medicare Trust Fund (reduced dollar spending) are expressed as negative numbers. All numbers are in millions. The costs in this table are true costs reflecting increased consumption of services and goods. However, the savings (reduced dollar spending) to the Medicare Trust Funds reflect a transfer from MA plans, Part D sponsors, and enrollees, who increase their spending, to the Trust Fund.

Table 21 combines related provisions. For example, all PACE provisions in the COI summary table are combined into one line item. Similarly, the paperwork burden of the LI NET provision in the COI Summary Table is combined with the drug costs listed in Table 17 into one line item.

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TABLE 21: SUMMARY OF COST AND TRANSFERS BY PROVISION AND YEAR*

	2024 Cost	2025 Cost	2026 Cost	2027 Cost	2027 Transfers	2028 Cost	2028 Transfers	2029 Costs	2029 Transfers	2030 Cost	2030 Transfers	2031 Cost	2031 Transfers	2032 Cost	2032 Transfers	2033 Cost	2033 Transfers	Raw 10 Year Totals
Total Costs	529.3	527.8	541.8	556.8		570.8		587.8		604.8		620.8		638.8		657.8		5,836.5
Savings of the Medicare Trust Fund					(2,410.0)		(2,980.0)		(3,280.0)		(3,560.0)		(3,860.0)		(4,310.0)		(4,570.0)	(24,970.0)
Translation (FIDE, HIDE SNPS)	2.1		-	-		-		-		-		-		-		-		2.1
Translation (Standing request)	10.4																	10.4
Low Income NET program	5.3	7.3	8.3	9.3		9.3		10.3		11.3		11.3		12.3		13.3		97.6
Prior Authorization	1.0	1.0	1.0	1.0		1.0		1.0		1.0		1.0		1.0		1.0		10.1
MTM Eligibility	336.1	336.1	336.1	336.1		336.1		336.1		336.1		336.1		336.1		336.1		3,361.2
Formulary changes	2.2	2.2	2.2	2.2		2.2		2.2		2.2		2.2		2.2		2.2		21.6
Reinstatement notices	0.3	0.3	0.3	0.3		0.3		0.3		0.3		0.3		0.3		0.3		2.9
Involuntary Disenrollment: Loss of Special Needs Status	0.5	0.5	0.5	0.5		0.5		0.5		0.5		0.5		0.5		0.5		4.9
Star Ratings					(2,410.0)		(2,980.0)		(3,280.0)		(3,560.0)		(3,860.0)		(4,310.0)		(4,570.0)	(24,970.0)
PACE Provisions	3.0	1.5	1.5	1.5		1.5		1.5		1.5		1.5		1.5		1.5		16.9
Marketing Provisions	0.17	0.17	0.17	0.17		0.17		0.17		0.17		0.17		0.17		0.17		1.7
Medical Necessity Determinations	(1.24)	(1.24)	(1.24)	(1.24)		(1.24)		(1.24)		(1.24)		(1.24)		(1.24)		(1.24)		(12.4)
Notification of Provider Terminations	0.5	0.52	0.52	0.52		0.52		0.52		0.52		0.52		0.52		0.52		5.2
Expansion of low-income subsidies	169.00	180.00	193.00	207.00		221.00		237.00		253.00		269.00		286.00		304.00		2,319.0

*Numbers are in millions. Costs are positive numbers while savings (reduced dollar spending) of the Medicare Trust Fund are expressed as negative numbers. Note: These estimates reflect a nondoubling of wages to account for fringe benefits for enrollees. Had we doubled wages for enrollees then the annual impact of the low coverage provision would increase by 0.26 million annually.

Notes to the summary table:

*Raw 10-year totals are found in the right most column. Monetized annual amounts are found in the accounting table.

**Almost all individual entries are costs. However, the medical necessity determinations are a savings. Since this is the only item that was a savings it was not believe necessary to create a new column of savings. Consequently, these savings are listed with the costs as negative numbers. The actual computations were presented in the section VIII. of this rule.

***There are 3 provisions that impact the Medicare Trust Fund:

(i) The Star Rating provision is estimated to save $25.0 billion over 10 years. These savings are transfers.

(ii) The low-income NET program will cost (increase spending of) the Medicare Trust Fund $95 million over 10 years (the $97.6 figure actually mentioned reflects an extra 2.6 million in paperwork burden).

(iii) The expansion of low-income subsidies with cost (increase spending of the Medicare Trust Fund) $2.3 billion over 10 years.

Both items (ii) and (iii) reflects actual costs not transfers; they reflect the costs of increased benefits by plans which are passed over to the Trust Fund. The net impact to the Trust Fund over 10 years is $22.6 billion in savings (decreased spending).

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G. Conclusion

As indicated in Table 19 the star rating provisions whose impact begins in 2027 reduces dollar spending of the Medicare Trust Fund by $22.6 billion over 10 years. This is offset by the paperwork costs of this rule which amount to $3.5 billion over 10 years. The major driver of the paperwork costs is the MTM provisions. Over an infinite horizon the aggregate costs of this rule expressed in 2016 dollars is $384 million per year. In accordance with requirements, this major rule has been reviewed by OMB.

IX. Response 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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 2, 2022.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, and Privacy.

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, Health facilities, Health maintenance organizations (HMO), Incorporation by reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 170

Computer technology, Health, Health care, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Public health, Reporting and recordkeeping requirements, Security measures.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV and the Department of Health and Human Services proposes to amend 45 CFR part 170 as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5) and sec. 105, Pub. L. 114–10, 129 Stat. 87.

■ 2. Section 401.305 is amended by revising paragraph (a)(2) to read as follows:

§ 401.305 Requirements for reporting and returning of overpayments.

(a) * * *

(1) * * *

(2) A person has identified an overpayment when the person knowingly receives or retains an overpayment. The term ''knowingly'' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

Subpart K—Enrollment, Entitlement, and Disenrollment under Medicare Contract

■ 3. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 4. Section 417.454 is amended by revising paragraph (e)(4) to read as follows:

§ 417.454 Charges to Medicare Enrollees.

* * * * *

(e) * * *

(4) A COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

■ 5. Section 417.460 is amended by revising paragraphs (c)(3) and (e)(2) and (4) and adding paragraph (e)(7) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS (or a third party to which CMS has assigned this responsibility, such as an HMO or CMP) may reinstate enrollment in the plan, without interruption of coverage, if the individual submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date, has not previously requested reinstatement for good cause during the same 60 day period following the involuntary disenrollment, shows good cause for failure to pay, and pays all overdue premiums or other charges within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums or other charges was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(e) * * *

(2) *Effort to resolve the problem.* The HMO or CMP must make a serious effort to resolve the problem presented by the enrollee, including the use (or attempted use) of internal grievance procedures, and including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. The HMO or CMP must inform the individual of the right to use the organization's grievance procedures, through the notices described in paragraph (e)(7) of this section.

* * * * *

(4) *Documentation.* The HMO or CMP must document the problems, efforts, and medical conditions as described in paragraphs (e)(1) through (3) of this section. Dated copies of the notices required in paragraph (d)(2)(iv) of this section must also be submitted to CMS.

* * * * *

(7) *Other required notices.* The HMO or CMP must provide the individual two notices prior to submitting the request for disenrollment to CMS. The first notice, the advance notice, informs the

member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action. If the disruptive behavior ceases after the enrollee receives the advance notice and then later resumes, the HMO or CMP must begin the process again. The HMO or CMP must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-days period the individual has the to provide an opportunity for the individual to cease their behavior. The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the enrollee that the HMO or CMP will request CMS permission to involuntarily disenroll the enrollee. This notice must be provided prior to submission of the request to CMS.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 6. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh

■ 7. Section 422.2 is amended by—

■ a. Adding definitions in alphabetical order for ''Chronic Condition Special Needs Plan'', ''Facility-based Institutional Special Needs Plan'', ''Hybrid Institutional Special Needs Plan'', ''Institutional-equivalent Special Needs Plan'', and ''Institutional Special Needs Plan''; and

■ b. Revising the definition of ''Severe or disabling chronic condition''.

The additions and revision read as follows:

§ 422.2 Definitions.

* * * * *

Chronic Condition Special Needs Plan (C–SNPs) means a SNP that restricts enrollment to MA eligible individuals who have one or more severe or disabling chronic conditions, as defined under this section, including restricting enrollment based on the multiple commonly co-morbid and clinically-linked condition groupings specified in § 422.4(a)(1)(iv) of this chapter.

* * * * *

Facility-based Institutional special needs plan (FI–SNP) means a type of I–SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized; owns or contracts with at least one institution, specified in the definition of institutionalized in this section, for each county within the plan's county-based service area; and must own or have a contractual arrangement with each institutionalized facility serving enrollees in the plan.

* * * * *

Hybrid Institutional special needs plan (HI–SNP) means a type of I–SNP that restricts enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent in this section. HI–SNPs must meet the standards specified in the definitions of FI–SNP and IE–SNP.

* * * * *

Institutional-equivalent special needs plan (IE–SNP) means a type of I–SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized-equivalent in this section.

* * * * *

Institutional special needs plan (I–SNP) means a SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent in this section. I–SNPs include the following subtypes: IE–SNP, HI–SNP, and FI–SNP

* * * * *

Network-based plan is defined as a coordinated care plan as specified in § 422.4(a)(1)(ii), a network-based MSA plan, or a section 1876 reasonable cost plan. A network-based plan excludes an MA regional plan that meets access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts.

* * * * *

Severe or disabling chronic condition means, for the purpose of defining a special needs individual, the following co-morbid and medically complex chronic conditions that are life-threatening or significantly limit overall health or function, has a high risk of hospitalization or other significant adverse health outcomes, and requires intensive care coordination, and that which is designated by the Secretary under subsections 1859(b)(6)(B)(iii)(II) and 1859(f)(9)(A) of the Act:

(1) Chronic alcohol use disorder and other substance use disorders (SUDs).

(2) Autoimmune disorders:

(i) Polyarteritis nodosa.

(ii) Polymyalgia rheumatica.

(iii) Polymyositis.

(iv) Dermatomyositis.

(v) Rheumatoid arthritis.

(vi) Systemic lupus erythematosus.

(vii) Psoriatic arthritis.

(viii) Scleroderma.

(3) Cancer.

(4) Cardiovascular disorders:

(i) Cardiac arrhythmias.

(ii) Coronary artery disease.

(iii) Peripheral vascular disease.

(iv) Valvular heart disease.

(5) Chronic heart failure.

(6) Dementia.

(7) Diabetes mellitus.

(8) Overweight, obesity, and metabolic syndrome.

(9) Chronic gastrointestinal disease:

(i) Chronic liver disease.

(ii) Non-alcoholic fatty liver disease (NAFLD)

(iii) Hepatitis B.

(iv) Hepatitis C

(v) Pancreatitis.

(vi) Irritable bowel syndrome.

(vii) Inflammatory bowel disease.

(10) Chronic kidney disease (CKD):

(i) CKD requiring dialysis/End-stage renal disease (ESRD).

(ii) CKD not requiring dialysis.

(11) Severe hematologic disorders:

(i) Aplastic anemia.

(ii) Hemophilia.

(iii) Immune thrombocytopenic purpura.

(iv) Myelodysplastic syndrome.

(v) Sickle-cell disease (excluding sickle-cell trait).

(vi) Chronic venous thromboembolic disorder.

(12) HIV/AIDS;

(13) Chronic lung disorders:

(i) Asthma, Chronic bronchitis.

(ii) Cystic Fibrosis.

(iii) Emphysema.

(iv) Pulmonary fibrosis.

(v) Pulmonary hypertension.

(vi) Chronic Obstructive Pulmonary Disease (COPD).

(14) Chronic and disabling mental health conditions:

(i) Bipolar disorders.

(ii) Major depressive disorders.

(iii) Paranoid disorder.

(iv) Schizophrenia.

(v) Schizoaffective disorder.

(vi) Post-traumatic stress disorder (PTSD).

(vii) Eating Disorders.

(viii) Anxiety disorders.

(15) Neurologic disorders:

(i) Amyotrophic lateral sclerosis (ALS).

(ii) Epilepsy.

(iii) Extensive paralysis (that is, hemiplegia, quadriplegia, paraplegia, monoplegia).

(iv) Huntington's disease.

(v) Multiple sclerosis.

(vi) Parkinson's disease.

(vii) Polyneuropathy.

(viii) Fibromyalgia.

(ix) Chronic fatigue syndrome.

(x) Spinal cord injuries.

(xi) Spinal stenosis.

(xii) Stroke-related neurologic deficit.

(16) Stroke.
(17) Post-organ transplantation care.
(18) Immunodeficiency and Immunosuppressive disorders.
(19) Conditions associated with cognitive impairment:
(i) Alzheimer's disease.
(ii) Intellectual disabilities and developmental disabilities.
(iii) Traumatic brain injuries.
(iv) Disabling mental illness associated with cognitive impairment.
(v) Mild cognitive impairment.
(20) Conditions with functional challenges and require similar services including the following: spinal cord injuries, paralysis, limb loss, stroke, and arthritis;
(21) Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell.
(22) Conditions that require continued therapy services in order for individuals to maintain or retain functioning.
* * * * *

■ 8. Section 422.4 is amended by adding paragraphs (a)(1)(iv)(A) and (B) to read as follows:

§ 422.4 Types of MA plans.

(a) * * *
(1) * * *
(iv) * * *
(A) A C–SNP may focus on one severe or disabling chronic condition, as defined in § 422.2, or on a grouping of severe or disabling chronic conditions.
(B) Upon CMS approval, an MA organization may offer a C–SNP that focuses on multiple commonly co-morbid and clinically-linked conditions from the following list of groupings:
(*1*) Diabetes mellitus and chronic heart failure.
(*2*) Chronic heart failure and cardiovascular disorders.
(*3*) Diabetes mellitus and cardiovascular disorders.
(*4*) Diabetes mellitus, chronic heart failure, and cardiovascular disorders.
(*5*) Stroke and cardiovascular disorders.
(*6*) Anxiety associated with COPD.
(*7*) Chronic kidney disease (CKD) and post-(renal) organ transplantation.
(*8*) Substance use disorders (SUD) and chronic mental health disorders.
* * * * *

■ 9. Section 422.52 is amended by adding paragraph (g) to read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

* * * * *

(g) *Special eligibility rule for certain C–SNPs.* For C–SNPs that use a group of multiple severe or disabling chronic conditions as described in § 422.4(a)(1)(iv) of this chapter, special needs individuals need only have one of the qualifying severe or disabling chronic conditions in order to be eligible to enroll.

■ 10. Section 422.60 is amended by adding paragraph (h) to read as follows:

§ 422.60 Election process.

* * * * *

(h) *Notification of reinstatement based on beneficiary cancellation of new enrollment.* When an individual is disenrolled from an MA plan due to the election of a new plan, the MA organization must reinstate the individual's enrollment in that plan if the individual cancels the election in the new plan within timeframes established by CMS. The MA organization offering the plan from which the individual was disenrolled must send the member notification of the reinstatement within 10 calendar days of receiving confirmation of the individual's reinstatement.

■ 11. Section 422.62 is amended by—
■ a. Adding a sentence to the end of paragraph (b)(2);
■ b. Revising paragraph (b)(18) introductory text;
■ c. Redesignating paragraphs (b)(18)(i) through (iii) as paragraphs (b)(18)(ii) through (iv);
■ d. Adding new paragraph (b)(18)(i);
■ e. Redesignating paragraph (b)(26) as paragraph (b)(27); and
■ f. Adding new paragraph (b)(26).

The additions and revision read as follows:

§ 422.62 Election of coverage under an MA plan

* * * * *

(b) * * *

(2) * * * Also eligible for this SEP are individuals who, as a result of a change in permanent residence, have new MA plan options available to them.

* * * * *

(18) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for a SEP to make a MA enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. The SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, the date the incident automatically ends under applicable State or local law, or, if incident end date is not otherwise identified, the incident end date specified in paragraph (b)(18)(i) of this section.

(i) If the incident end date of an emergency or major disaster is not otherwise identified, the incident end date will be one year after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration, whichever is later. Therefore, the maximum length of this SEP, if the incident end date is not otherwise identified, is 14 full calendar months after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration.

* * * * *

(26) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR 406.27 and 407.23. The SEP begins when the individual submits their application for premium-Part A and Part B, or Part B only, and continues for the first 2 months of enrollment in Part A (premium or premium-free) and Part B. The MA plan enrollment is effective the first of the month following the month the MA plan receives the enrollment request.

* * * * *

■ 12. Section 422.66 is amended by adding paragraphs (b)(3)(v) and (b)(6) to read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(b) * * *
(3) * * *
(v) In the case of an incomplete disenrollment request—
(A) Document its efforts to obtain information to complete the disenrollment request;
(B) Notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request.
(C) The organization must deny the request if any additional information needed to make the disenrollment request ''complete'' is not received within the following timeframes:
(*1*) For disenrollment requests received during the AEP, by December 7, or within 21 calendar days of the request for additional information, whichever is later; and
(*2*) For disenrollment requests received during all other election periods, by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.

* * * * *

(6) *When a disenrollment request is considered incomplete.* A disenrollment request is considered to be incomplete if the required but missing information

is not received by the MA organization within the timeframe specified in paragraph (b)(3)(v)(C)of this section.

* * * * *

■ 13. Section 422.74 is amended by—
■ a. Adding paragraph (b)(2)(vi);
■ b. Revising paragraphs (c), (d)(1)(i)(B)(*1*), and (d)(1)(v);
■ c. Revising paragraphs (d)(2)(iii) and (iv);
■ d. Adding paragraph (d)(2)(vii);
■ e. Revising paragraph (d)(4)(i);
■ f. Adding paragraphs (d)(4)(ii)(A), reserved (d)(4)(ii)(B), and (d)(4)(iii)(F);
■ g. Revising paragraph (d)(4)(iv)
■ h. Redesignating paragraph (d)(8) as paragraph (d)(9) and adding new paragraph (d)(8);
■ i. Adding paragraph (d)(10); and
■ j. Revising paragraph (e)(1).

The revisions and additions read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(b) * * *

(2) * * *

(vi) The individual no longer meets the MA MSA's eligibility criteria specified under § 422.56 due to a mid-year change in eligibility.

* * * * *

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i) and (vi), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(vi) must—

(1) Be provided to the individual before submission of the disenrollment to CMS; and

(2) Include an explanation of the individual's right to submit a grievance under the MA organization's grievance procedures.

(d) * * *

(1) * * *

(i) * * *

(B) * * *

(*1*) Be at least 2 whole calendar months; and

* * * * *

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as an MA organization) may reinstate enrollment in the MA plan, without interruption of coverage, if the individual—

(A) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date; and

(B) Has not previously requested reinstatement for good cause during the same 60 day period following the involuntary disenrollment; and

(C) Shows good cause for failure to pay within the initial grace period; and

(D) Pays all overdue premiums within 3 calendar months after the disenrollment date; and

(E) Establishes by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(2) * * *

(iii) *Effort to resolve the problem.* The MA organization must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. In addition, the MA organization must inform the individual of the right to use the organization's grievance procedures, through the notices described in paragraph (d)(2)(vii) of this section. The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation.* The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual. The MA organization must submit this information and any documentation received by the beneficiary to CMS. Dated copies of the notices required in paragraph (d)(2)(vii) of this section must also be submitted to CMS.

* * * * *

(vii) *Required notices.* The MA organization must provide the individual two notices prior to submitting the request for disenrollment to CMS. The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action. If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the organization must begin the process again. The organization must wait at least 30 days after sending the advance notice before sending the second notice, during which 30- day period the individual has the opportunity to cease their behavior. The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the MA organization will request CMS permission to involuntarily disenroll the member. This notice must be provided prior to submission of the request to CMS. These notices are in addition to the disenrollment submission notice required under paragraph (c) of this section.

* * * * *

(4) * * *

(i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the MA organization must disenroll an individual, and must document the basis for such action, if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved—

* * * * *

(ii) * * *

(A) The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the US Postal Service as undeliverable and a forwarding address is not provided.

(B) [Reserved]

(iii) * * *

(F) The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the US Postal Service as undeliverable and a forwarding address is not provided.

* * * * *

(iv) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area or within the first 10 calendar days of the sixth month of an individual's temporary absence from the plan service area or, for individuals using a visitor/traveler benefit, within the first 10 calendar days of the last month of the allowable absence. If the plan learns of an individual's temporary absence from the plan service area after the expiration of the allowable period,

the plan must send this notice within 10 calendar days of the plan learning of the absence.

* * * * *

(8) *Loss of Special Needs Status.* If an enrollee loses special needs status and must be disenrolled under paragraph (b)(2)(iv) of this section, the SNP must provide the enrollee with a minimum of 30 days advance notice of disenrollment, regardless of the date of loss of special needs status.

(i) The advance notice must be provided to the enrollee within 10 calendar days of the plan learning of the loss of special needs status and must afford the enrollee an opportunity to prove that they are still eligible to remain in the plan.

(ii) The advance notice must include the disenrollment effective date, a description of eligibility for the SEP described in § 422.62(b)(11), and, if applicable, information regarding the period of deemed continued eligibility, the duration of the period of deemed continued eligibility, and the consequences of not regaining special needs status within the period of deemed continued eligibility.

(iii) A final involuntary disenrollment notice must be sent within 3 business days following the disenrollment effective date, which is either the last day of the period of deemed continued eligibility, if applicable, or a minimum of 30 days after providing the advance notice of disenrollment. The final involuntary disenrollment notice must be sent before submission of the disenrollment to CMS.

(iv) The final involuntary disenrollment notice must include an explanation of the enrollee's right to file a grievance under the MA organization's grievance procedures that are required by § 422.564.

* * * * *

(10) *Mid-year change in MSA eligibility.* If an individual is no longer eligible for an MA MSA plan due to a mid-year change in eligibility, disenrollment is effective the first day of the calendar month following the MA organization's notice to the individual that they are ineligible in accordance with paragraph (b)(2)(vi) of this section.

(e) * * *

(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B or mid-year loss of MSA eligibility.* An individual who is disenrolled under paragraph (b)(1)(i), (ii), or (iii), or *(b)(2)(ii)* or (vi) of this section is deemed to have elected original Medicare.

* * * * *

■ 14. Section 422.101 is amended by—

■ a. Revising paragraph (b)(2);
■ c. Adding paragraph (b)(6);
■ d. Revising paragraph (c);
■ e. Adding paragraph (f)(2)(vi);
■ f. Revising paragraph (f)(3)(iii); and
■ g. Adding paragraph (f)(3)(iv)

The revisions and additions read as follows:

§ 422.101 Requirements relating to basic benefits

* * * * *

(b) * * *

(2) General coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. For example, this includes coverage criteria for inpatient admissions at 42 CFR 412.3, requirements for coverage of Skilled Nursing Facility (SNF) Care and Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) coverage criteria at 42 CFR 412.622(3).

* * * * *

(6) When coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, MA organizations may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question. For internal coverage policies, the MA organization must provide:

(i) A publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;

(ii) A list of the sources of such evidence; and

(iii) Include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination.

(c) Medical necessity determinations and special coverage provisions— (1) *Medical necessity determinations.* (i) MA organizations must make medical necessity determinations based on:

(A) Coverage and benefit criteria as specified at paragraphs (b) and (c) of this section and may not deny coverage for basic benefits based on coverage criteria not specified in paragraph (b) or (c) of this section;

(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act;

(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and

(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

(ii) [Reserved]

(2) *Exception for qualifying hospital stay.* MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of posthospital SNF care as described in subparts C and D of this part, in the absence of the prior qualifying hospital stay that would otherwise be required for coverage of this care.

* * * * *

(f) * * *

(2) * * *

(vi) For I–SNPs, ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in § 422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized.

(3) * * *

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent and each MOC must meet an aggregate minimum benchmark of 70 percent, and a plan's model of care will only be approved if each element of the model of care meets the minimum benchmark and the model of care meets aggregate minimum benchmark.

(A) An MOC for a C–SNP that receives a passing score is approved for 1 year.

(B) An MOC for an I–SNP or D–SNP that receives an aggregate minimum benchmark score of 85 percent or greater is approved for 3 years. An MOC for an I–SNP or D–SNP that receives a score of 75 percent to 84 percent is approved for 2 years. An MOC for an I–SNP or D–SNP that receives a score of 70 percent to 74 percent is approved for 1 year.

(C) For an MOC that fails to meet a minimum element benchmark score of 50 percent or an MOC that fails to meet the aggregate minimum benchmark of 70 percent, the MA organization is permitted a one-time opportunity to resubmit the corrected MOC for reevaluation; and an MOC that is corrected and resubmitted using this cure period is approved for only 1 year.

(iv) An MA organization that offers a SNP that seeks to revise the MOC before the end of the MOC approval period may submit changes to the MOC as off-cycle MOC submissions for review by NCQA as follows:

(A) D–SNPs and I–SNPs may submit updates and corrections to their NCQA-approved MOC any number of times between June 1st and November 30th of each calendar year or when CMS requires an off-cycle submission to ensure compliance with applicable law.

(B) D–SNPs and I–SNPs are required to submit updates or corrections as part of an off-cycle submissions based on:

(*1*) Substantial changes in policies or procedures pertinent to: the health risk assessment (HRA) process; revising processes to develop and update the Individualized Care Plan (ICP); the integrated care team process; risk stratification methodology; or care transition protocols;

(*2*) Target population changes that warrant modifications to care management approaches;

(*3*) Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related SNP operations;

(*4*) Changes in level of authority or oversight for personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel); or

(*5*) Changes to quality metrics used to measure performance.

(C) NCQA will only review off-cycle submissions after the start of the effective date of the current MOC unless CMS deems it necessary to ensure compliance with the applicable regulations.

(D) SNPs may not implement any changes to a MOC until NCQA has approved the changes and the MOC is not rescored during the off-cycle review of changes to the MOC.

(E) Successful revision of the MOC under paragraph (f)(3)(iii)(B) of this section does not change the MOC's original period of approval by NCQA.

(F) C–SNPs are only eligible to submit an off-cycle MOC submission when CMS requires an off-cycle submission to ensure compliance with applicable law.

(G) When a deficiency identified in the off-cycle revisions to a MOC, the SNP may cure the deficiency a single time between June 1st and November 30th of each calendar year.

■ 15. Section 422.109 is amended by revising the section heading and adding paragraphs (e) and (f) to read as follows:

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials

* * * * *

(e) *Clinical trials.* (1) With the exception specified in paragraph (e)(3) of this section, original Medicare is responsible for coverage of MA enrollees participating in CMS-approved clinical trials to include routine costs, as specified in NCD 310.1, and any coverage for the diagnosis or treatment of complications related to the clinical trial.

(2) MA enrollees are not charged traditional Medicare Part A and B deductibles for clinical trial coverage.

(3) MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services.

(4) An enrollee's in-network cost-sharing portion must be included in the MA plan's maximum out-of-pocket calculation.

(5) MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial.

(f) *A and B IDE trials.* (1) MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies that are covered under § 405.211(a) of this chapter.

(2) MA plans are responsible for coverage of CMS-approved Category B devices that are covered under § 405.211(b) of this chapter.

■ 16. Section 422.111 is amended by—

■ a. Revising paragraphs (b)(3)(i) and (e);

■ b. Revising pargraph (h)(1)(iii)(A); and

■ c. Revising paragraph (h)(1)(iv)(B).

The revisions and additions read as follows:

§ 422.111 Disclosure Requirements.

* * * * *

(b) * * *

(3) * * *

(i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office; notations for MOUD-Waivered Providers as defined in § 422.116(b)(1)(xxx) who are listed on the Substance Abuse and Mental Health Services Administration's Buprenorphine Practitioner Locator; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

* * * * *

(e) *Changes to provider network.* The MA organization must provide enrollees notice of a termination of a contracted provider, irrespective of whether the termination was for cause or without cause, in accordance with § 422.2267(e)(12). The MA organization must make a good faith effort to provide enrollees notice of a for-cause termination of a contracted provider within the timeframes required by this paragraph (e). For all terminations, the MA organization must meet the following requirements:

(1) For contract terminations that involve a primary care or behavioral health provider:

(i) Provide both written and telephonic notice,

(ii) At least 45 calendar days before the termination effective date, and

(iii) To all enrollees who have ever been patients of that primary care or behavioral health provider.

(2) For contract terminations that involve specialty types other than primary care or behavioral health:

(i) Provide written notice,

(ii) At least 30 calendar days before the termination effective date, and

(iii) To all enrollees who are patients seen on a regular basis by the provider whose contract is terminating. The phrase ''enrollees who are patients seen on a regular basis by the provider whose contract is terminating'' means enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated.

* * * * *

(h) * * *

(1) * * *

(iii) * * *

(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals. Such interpreters must:

(*1*) Adhere to generally accepted interpreter ethics principles, including confidentiality;

(*2*) Demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and

(*3*) Interpret effectively, accurately, and impartially, both receptively and

expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

* * * * *

(iv) * * *

(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

* * * * *

■ 17. Section 422.112 is amended by—

■ a. Adding a sentence at the end of paragraph (a)(1)(i);

■ b. Adding paragraph (a)(1)(iii);

■ c. Removing the last sentence of paragraph (a)(3);

■ d. Revising paragraphs (a)(6)(i) and (a)(8);

■ f. Revising paragraph (b)(3); and

■ g. Adding paragraphs (b)(8) and (9).

The additions and revisions read as follows:

§ 422.112 Access to services.

(a) * * *

(1) * * *

(i) * * * The network must include providers that specialize in behavioral health services.

* * * * *

(iii) Arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

* * * * *

(6) * * *

(i) Timeliness of access to care and member services that meet or exceed standards in this paragraph. The MA organization must continuously monitor access to care and member services and must take corrective action as necessary to ensure that appointment wait times in the provider network comply with these standards. The minimum standards for appointment wait times for primary care and behavioral health services are as follows for appointments:

(A) Urgently needed services or emergency—immediately;

(B) Services that are not emergency or urgently needed, but the enrollee requires medical attention—within 1 week; and

(C) Routine and preventive care—within 30 days.

* * * * *

(8) *Ensuring equitable access to Medicare Advantage (MA) Services.* Ensure that services are provided in a culturally competent manner and to promote equitable access to all enrollees, including the following:

(i) People with limited English proficiency or reading skills.

(ii) People of ethnic, cultural, racial, or religious minorities.

(iii) People with disabilities.

(iv) People who identify as lesbian, gay, bisexual, or other diverse sexual orientations.

(v) People who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex.

(vi) People living in rural areas and other areas with high levels of deprivation.

(vii) People otherwise adversely affected by persistent poverty or inequality.

* * * * *

(b) * * *

(3) Programs for coordination of plan services with community and social services generally available through contracting or noncontracting providers in the area served by the MA plan, including nursing home and community-based services, and behavioral health services; and

* * * * *

(8)(i) With respect to basic benefits, policies for using prior authorization that at a minimum include that for enrollees undergoing an active course of treatment—

(A) Approval of a prior authorization request for a course of treatment is valid for the entire duration of the approved course of treatment; and

(B) A minimum 90-day transition period for any active course(s) of treatment when an enrollee has enrolled in an MA plan after starting a course of treatment, even if the service is furnished by an out-of-network provider. This includes enrollees new to a plan and enrollees new to Medicare. The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

(ii) For purposes of this paragraph (b)(8), the following definitions apply:

(A) *Course of treatment* means as a prescribed order or ordered course of treatment for a specific individual with a specific condition is outlined and decided upon ahead of time with the patient and provider. A course of treatment may but is not required to be part of a treatment plan.

(B) *Active course of treatment* means a course of treatment in which a patient is actively seeing the provider and following the course of treatment.

(9) Procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in the same location using electronic exchange, as defined in § 422.135.

(i) The MA organization must make information about its digital health literacy screening and digital health education programs available to CMS upon request. Requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of this section.

(ii) [Reserved].

* * * * *

■ 18. Section 422.113 is amended by revising paragraph (b)(1)(i) introductory text to read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(1) * * *

(i) *Emergency medical condition* means a medical condition, mental or physical, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in –

* * * * *

■ 19. Section 422.114 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 422.114 Access to services under an MA private fee-for-service plan.

* * * * *

(a) * * *

(3) * * *

(ii) Network-based plan means a plan as defined in § 422.2.

* * * * *

■ 20. Section 422.116 is amended by —

■ a. Removing ''§ 422.114(a)(3)(ii)'' and adding ''§ 422.2'' in its place in paragraph (a)(1)(i);

■ b. Adding paragraphs (b)(1)(xxviii) through (xxx);

■ c. Adding in alphabetical order entries for ''Clinical Psychology'', ''Licensed Clinical Social Work'', and ''Prescribers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)'' to Table 1 to Paragraph (d)(2);

■ d. Adding paragraphs (d)(5)(xiii) through (xv); and
■ e. Adding in alphabetical order entries for ''Clinical Psychology'', ''Clinical Social Work'', and ''Prescribers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)'' to Table 2 to Paragraph (e)(3)(i)(C).

The revisions and additions read as follows:

§ 422.116 Network adequacy.

* * * * *

(b) * * *

(1) * * *

(xxviii) Clinical Psychology.

(xxix) Clinical Social Work.

(xxx) Prescribers of Medication for Opioid Use Disorder (MOUD) (including MOUD- Waivered Providers and/or Opioid Treatment Programs (OTPs)). For purposes of this regulation, MOUD-Waivered Providers means providers who are waived by the Substance Abuse and Mental Health Services Administration and the Drug Enforcement Agency to administer, dispense, or prescribe narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment for opioid use disorder in accordance with section 303(g)(2) of the Controlled Substances Act, and OTPs means OTPs as defined in section 1861(jjj)(2) of the Act.

* * * * *

(d) * * *

(2) * * *

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
* *		*		*	*		*		*	
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
* *		*		*	*		*		*	
Licensed Clinical Social Work	20	10	30	20	50	35	75	60	125	110
* *		*		*	*		*		*	
Prescribers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)	20	10	30	20	50	35	75	60	110	100
* *		*		*	*		*		*	

* * * * *

(5) * * *

(xiii) Clinical Psychology.

(xxiv) Clinical Social Work.

(xv) Providers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)

* * * * *

(e) * * *

(3) * * *

(i) * * *

(C) * * *

TABLE 2 TO PARAGRAPH (e)(3)(i)(C)

Minimum ratio	Large metro	Metro	Micro	Rural	CEAC
* * * *	*		*		*
Clinical Psychology	0.15	0.15	0.13	0.13	0.13
Clinical Social Work	0.25	0.25	0.22	0.22	0.22
* * * *	*		*		*
Prescribers of Medication for Opioid Use Disorder (including MOUD-Waivered Providers and/or OTPs)	0.03	0.03	0.03	0.03	0.03

* * * * *

■ 21. Section 422.137 is added to read as follows:

§ 422.137 Medicare Advantage Utilization Management Committee

(a) *General.* An MA organization that uses utilization management (UM) policies and procedures, including prior authorization (PA), must establish a UM committee that is led by a plan's medical director (described in § 422.562(a)(4)).

(b) *Limit on use of UM policies and procedures.* An MA plan may not use any UM policies and procedures for basic or supplemental benefits on or after January 1, 2024 unless those policies and procedures have been reviewed and approved by the UM committee.

(c) *Utilization Management Committee Composition.* The UM committee must—

(1) Include a majority of members who are practicing physicians.

(2) Include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan.

(3) Include at least one practicing physician who is an expert regarding care of elderly or disabled individuals.

(4) Include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies.

(d) *Utilization Management Committee Responsibilities.* The UM committee must—

(1) At least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. Such review must consider:

(i) The services to which the utilization management applies;

(ii) Coverage decisions and guidelines for Traditional Medicare, including NCDs, LCDs, and laws; and

(iii) Relevant current clinical guidelines.

(2) Approve only utilization management policies and procedures that:

(i) Use or impose coverage criteria that comply with the requirements and standards at § 422.101(b);

(ii) For prior authorization policies, comply with requirements and standards at § 422.138;

(iii) Comply with the standards in § 422.202(b)(1); and

(iv) Apply and rely on medical necessity criteria that comply with § 422.101(c)(1).

(3) Revise the utilization management policies and procedures as necessary to comply with the standards in this regulation, including removing requirements for UM for services and items that no longer warrant UM.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

■ 22. Section 422.138 is added to read as follows:

§ 422.138 Prior authorization.

(a) *Requirement.* When a coordinated care plan, as specified in § 422.4(a)(iii) (including MSA network plans), uses prior authorization processes in connection with basic benefits or supplemental benefits, the MA organization must comply with the requirements in this section. (MA PFFS are not permitted to use prior authorization policies or ''prior notification'' policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS plan in advance that services will be furnished).

(b) *Application.* Prior authorization policies and procedures for coordinated care plans may only be used for one or more the following purposes:

(1) To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; or

(2) For basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1), or

(3) For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

(c) *Effect of prior authorization or pre-service approval.* If the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity unless the MA organization has the authority to reopen the decision for good cause or fraud or similar fault per the reopening provisions at § 422.616.

■ 23. Section 422.152 is amended by adding paragraph (a)(5) to read as follows:

§ 422.152 Quality Improvement Program.

(a) * * *

(5) Incorporate one or more activities that reduce disparities in health and health care. These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.

* * * * *

■ 24. Section 422.162 is amended by—

■ a. Adding in alphabetical order to paragraph (a) a definition for ''health equity index''; and

■ b. Revising paragraphs (b)(1) and (b)(3)(iv)(A)(*1*).

The addition and revisions read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

* * * * *

(b)(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with § 422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 422.166(c), with both the reward factor and CAI applied as applicable, as described in § 422.166(f). Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 422.166(d) with both the reward factor and CAI applied as applicable, as described in § 422.166(f). CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

* * * * *

(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, call center measures, and improvement measures. The survey-based measures will 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. The Part C and D improvement measures are not calculated for first year consolidations.

* * * * *

■ 25. Section 422.164 is amended by revising paragraph (d)(1)(v) and adding paragraph (e)(1)(iii) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(d) * * *

(1) * * *

(v) Add alternative data sources or expand modes of data collection.

* * * * *

(e) * * *

(1) * * *

(iii) The measure steward other than CMS retires a measure.

* * * * *

■ 26. Section 422.166 is amended by—

■ a. Revising paragraphs (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii) and (iv), (e)(2), (f)(1) introductory text, and (f)(2)(i) introductory text;

■ b. Adding paragraph (f)(3); and

■ c. Revising paragraphs (g)(1), (i)(3)(iv), (i)(9)(i), and (i)(10)(i).

The revisions and addition 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. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 through October 2024, CMS will add 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. 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.

* * * * *

(c) * * *

(1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(d) * * *

(1) The overall rating for a MA–PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

* * * * *

(2) *Rules for new and substantively updated measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. Substantively updated measures will receive a weight of 1 in their first year returning to the Star Ratings after being on the display page. In subsequent years, the measure will be assigned the weight associated with its category.

* * * * *

(f) * * *

(1) *Reward factor.* Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

* * * * *

(2) * * *

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

* * * * *

(3) *Health equity index.* Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA–PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA–PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA–PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low income subsidy or being dual eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings would be adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Data are used for contracts that have data for only the most recent year of the 2 years, but data are not used for contracts that have data for only the first of the 2 years.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA–PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the health equity index. CMS will announce the measures being evaluated for inclusion in the calculation of the health equity index under this paragraph (f)(3) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's health equity index, the measure must meet the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees in the contract with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each measure for the subset enrollees that have one or more of the specified SRFs will be assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving −1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all

measures included in the index using the Star Ratings measure weight for each measure divided by the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the health equity index and 0.4 if the contract receives a score of 1 on the health equity index. For contracts that have percentages of enrollees with SRFs greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the health equity index reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the health equity index and 0.2 if the contract receives a score of 1 on the HEI. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have an HEI score calculated (that is, contracts that are not scored on at least half of the measures included in the index) would not receive a HEI reward.

(ix) The HEI reward is added to the overall rating, Part C rating for MA–PDs and MA-only contracts (and cost contracts), Part D rating for MA–PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

* * * * *

(g) * * *

(1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA–PD contracts and Part C summary rating for MA-only contracts), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) If the highest rating for each contract-type is 5 stars without the use of the improvement measure(s) and with the reward factor adjustment if applicable and the CAI adjustment under paragraph (f) of this section, a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating is less than 5 stars without the use of the improvement measure(s) and with the reward factor adjustment if applicable and CAI adjustment, the rating will be calculated with the improvement measure(s).

* * * * *

(i) * * *

(3) * * *

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure. The adjustment is for 3 years after the extreme and uncontrollable circumstance.

* * * * *

(9) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

* * * * *

(10) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

* * * * *

■ 27. Section 422.202 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 422.202 Participation procedures.

(b) * * *

(1) * * *

(i) Are based on current evidence in widely used treatment guidelines or clinical literature;

* * * * *

■ 28. Section 422.254 is amended by adding paragraph (a)(5) to read as follows.

§ 422.254 Submission of bids.

(a) * * *

(5) After an MA organization is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 422.2263(a)), the MA organization shall not change and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined in § 422.162) for the following contract year without modification, except where a modification in benefits is required by law. This prohibition on changes applies to cost sharing and premiums as well as benefits.

* * * * *

■ 29. Section 422.260 is amended by –
■ a. Revising paragraphs (c)(1)(i) and (c)(2)(v);
■ b. Adding paragraph (c)(3)(iii); and
■ c. Revising paragraph (d).

The revisions and addition read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

* * * * *

(c) * * *

(1) * * *

(i) The MA organization requesting reconsideration of its QBP status must do so by providing written notice to CMS within 10 business days of the release of its QBP status. The request must specify the given measure(s) in question and the basis for reconsideration such as a calculation error or incorrect data was used to determine the QBP status. Requests are limited to those circumstances where the error could impact an individual measure's value or the overall Star Rating. Based on any corrections, any applicable measure-level Star Ratings could go up, stay the same, or go down. The overall Star Rating also may go up, stay the same, or go down based on any corrections.

* * * * *

(2) * * *

(v) The MA organization must prove by a preponderance of evidence that CMS' calculations of the measure(s) and value(s) in question were incorrect. The burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status.

* * * * *

(3) * * *

(iii) The MA organization may not request a review based on data inaccuracy for the following data sources: HEDIS, CAHPS, HOS, Part C and D Reporting Requirements, PDE, Medicare Plan Finder pricing files, data from the Medicare Beneficiary Database Suite of Systems, Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources.

* * * * *

(d) *Reopening of QBP determinations.* CMS may, on its own initiative, revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year. CMS may take this action on the basis of any credible information, including the information provided during the administrative review process that demonstrates that the initial QBP determination was incorrect. If a contract's QBP determination is reopened as a result of a systemic calculation issue that impacts more than the MA organization that submitted an appeal, the QBP rating for MA organizations that did not appeal will only be updated if it results in a higher QBP rating.

■ 30. Section 422.326 is amended by revising paragraph (c) to read as follows:

§ 422.326 Reporting and returning of overpayments.

* * * * *

(c) *Identified overpayment.* The MA organization has identified an overpayment when the MA organization knowingly receives or retains an overpayment. The term ''knowingly'' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

* * * * *

■ 31 Section 422.500 is amended by adding in alphabetical order to paragraph (b) definitions for ''Final Settlement Adjustment Period'', ''Final Settlement Amount'', and ''Final Settlement Process'' to read as follows:

§ 422.500 Scope and Definitions.

* * * * *

(b) * * *

Final settlement adjustment period means the period of time between when the contract terminates and the date the MA organization is issued a notice of the final settlement amount.

Final settlement amount is the final payment amount that CMS owes and ultimately pays to an MA organization, or that an MA organization owes and ultimately pays to CMS, with respect to an MA contract that has consolidated, non-renewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(i) Risk adjustment reconciliation (described in § 422.310);

(ii) Part D annual reconciliation (described in § 423.343);

(iii) Coverage Gap Discount Program annual reconciliation (described in § 423.2320) and;

(iv) MLR remittances (described in §§ 422.2470 and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS calculates the final settlement amount, issues the final settlement amount along with supporting documentation in the notice of final settlement to the MA organization, receives responses from the MA organization requesting an appeal of the final settlement amount, and takes final actions to adjudicate an appeal (if requested) and make payments to or receive payments from the MA organization. The final settlement amount will be calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

* * * * *

■ 32. Section 422.502 is amended by adding paragraph (a)(3) to read as follows:

§ 422.502 Evaluation and determination procedures.

(a) * * *

(3)(i) CMS does not evaluate or issue a notice of determination described in paragraph (c) of this section when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 422.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

* * * * *

■ 33. Section 422.503 is amended by revising paragraphs (e)(1) and (2) to read as follows:

§ 422.503 General provisions.

* * * * *

(e) * * *

(1) The contract will be amended to exclude any MA plan, MA plan segment, or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan, segment, or entity will be deemed to be in place when such a request is made.

■ 34. Section 422.504 is amended by adding paragraph (a)(19) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(19) Not to establish a segment of an MA plan that meets the criteria in § 422.514(d), as determined in the procedures described in § 422.514(e)(3),

with the addition of the newly enrolled individuals.

* * * * *

■ 35. Section 422.510 is amended by adding paragraph (a)(4)(xvi) to read as follows:

§ 422.510 Termination of contract by CMS.

* * * * *

(a) * * *

(4) * * *

(xvi) Meets the criteria in § 422.514(d)(1) or (2).

* * * * *

■ 36. Section 422.514 is amended by revising paragraph (d)(1) and adding paragraph (g) to read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(d) * * *

(1) Enter into or renew a contract under this subpart, for plan year 2024 and subsequent years, for a MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) 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.

* * * * *

(g) *Applicability to segments.* The rules under paragraphs (d) through (f) of this section also apply to segments of the MA plan as provided for local MA plans under § 422.262(c)(2).

■ 32. Section 422.528 is added to read as follows:

§ 422.528 Final settlement process and payment

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the MA organization a notice of final settlement. The notice of final settlement contains at least the following information:

(1) A final settlement amount, which may be either an amount due to the MA organization, or an amount due from the MA organization, or $0 if nothing is due to or from the MA organization, for the contract that has been consolidated, nonrenewed, or terminated;

(2) Relevant banking and financial mailing instructions for MA organizations that owe CMS a final settlement amount;

(3) Relevant CMS contact information, and;

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 422.529.

(b) *Request for an appeal.* An MA organization that disagrees with the final settlement amount will have 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 422.529.

(1) If a MA organization agrees with the final settlement amount, no response is required.

(2) If an MA organization disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS will not consider subsequent requests for appeal.

(c) *Actions if a MA organization does not request an appeal.* (1) For MA organizations that are owed money by CMS, CMS will remit payment to the MA organization within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For MA organizations that owe CMS money, the MA organization will be required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the MA organization fails to remit payment within that 120-calendar-day period, CMS will refer the debt owed to CMS to the Department of Treasury for collection.

(d) *Actions following submission of a request for appeal.* If an MA organization responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS will conduct a review under the process described at§ 422.529.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under paragraph (a) of this section, is issued to the MA organization, CMS will no longer apply retroactive payment adjustments to the terminated, consolidated or nonrenewed contract and there will be no adjustments applied to amounts used in the calculation of the final settlement amount.

■ 33. Section 422.529 is added to read as follows:

§ 422.529 Requesting an appeal of the final settlement amount

(a) *Appeals process.* If an MA organization does not agree with the final settlement amount described in § 422.528(a) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the final settlement amount described in § 422.528(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 calendar days from the date that CMS issued the notice of final settlement to the MA organization.

(ii) *Content of request.* The written request for reconsideration must:

(A) Specify the calculations with which the MA organization disagrees and the reasons for its disagreement,

(B) include evidence supporting the assertion that CMS' calculation of the final settlement amount is incorrect, and

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) CMS provides a copy of the record that was before CMS when CMS made its decision to the hearing officer.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review will be conducted in the following manner:

(i) *Manner and timing of request.* An MA organization that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (2)(iv) of this section. An MA organization may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Administrator's review.* If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The MA organization's appeal is limited to CMS' calculation of the final settlement amount. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The MA organization bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

(c) *Stay of financial transaction until appeals are exhausted.* If an MA organization requests review of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount will be stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the MA organization fails to request further review within the applicable 15-calendar-day timeframe, CMS will communicate with the MA organization to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

(d) *Continued compliance with other law required.* Nothing in this section limits an MA organization's responsibility to comply with any other applicable statute or regulation, including under section 1128J(d) of the Social Security Act.

■ 34. Section 422.550 is amended by revising paragraph (d) to read as follows:

§ 422.550 General provisions.

* * * * *

(d) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The current MA organization, with respect to the affected contract, has substantially failed to comply with the regulatory requirements pursuant to § 422.510(a)(4)(ix) and the contract may be subject to intermediate enrollment and marketing sanctions as outlined in § 422.750(a)(1) and (3); intermediate sanctions imposed as part of this section will remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i) If the new owner does not participate in the Medicare program in the same service area as the affected contract, it must apply for, and enter into, a contract in accordance with subpart K of this part and part 423 of this chapter if applicable; and, if the application is conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under paragraph (c) of this section for review and approval by CMS; or

(ii) If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions as outlined in (d)(1) of this section, submit the documentation required under paragraph (c) of this section for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (d)(1)(i) or (ii) of this section within 30 days of imposition of intermediate sanctions as outlined in paragraph (d)(1) of this section, the existing contract will be subject to termination in accordance with § 422.510(a)(4)(ix).

* * * * *

■ 35. Section 422.566 is amended by revising paragraph (d) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

■ 36. Section 422.590 is amended by revising paragraph (b)(1) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(b) * * *

(1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)(2)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

* * * * *

■ 37. Section 422.629 is amended by revising paragraph (k)(3) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(k) * * *

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. Any physician or other health care professional who reviews an integrated organization determination must have a current and unrestricted license to practice within the scope of his or her profession.

* * * * *

■ 38. Section 422.760 is amended by revising paragraph (b)(3) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(3)(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.

(ii) *Calculation of penalty amounts.* (A) CMS will set minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(B) CMS will announce the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(C) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

* * * * *

■ 39. Section 422.2261 is amended by revising paragraph (a)(2) and removing paragraph (a)(3).

The revision reads as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) * * *

(2) Materials must be submitted to the HPMS Marketing Module by the MA organization or, where materials have been developed by a Third Party Marketing Organization for multiple MA organizations or plans, by a Third Party Marketing Organization with prior approval of each MA organization on whose behalf the materials were created.

* * * * *

■ 40. Section 422.2262 is amended by revising paragraph (a)(1)(ii) and adding paragraph (a)(1)(xix) to read as follows:

§ 422.2262 General communications materials and activity requirements.

* * * * *

(a) * * *

(1) * * *

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that has been published in either the current contract year or prior contract year.

* * * * *

(xix) Use the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card, in a misleading way.

* * * * *

■ 41. Section 422.2263 is amended by adding paragraphs (b)(8) through (10) to read as follows:

§ 422.2263 General marketing requirements.

* * * * *

(b) * * *

(8) Advertise benefits that are not available to beneficiaries in the service area where the marketing appears, unless unavoidable in a local market.

(9) Market any products or plans, benefits, or costs, unless the MA organization or marketing name(s) as listed in HPMS of the entities offering the referenced products or plans, benefits, or costs are identified in the marketing material.

(i) MA organization or marketing names must be in 12-point font in print and may not be in the form of a disclaimer or fine print.

(ii) For television, online, or social media, the MA organization or marketing name(s) must be either read at the same pace as the phone number or must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number or benefits.

(iii) For radio or other voice-based advertisements, MA organization or marketing names must be read at the same pace as the advertised phone numbers.

(10) MA organizations may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

* * * * *

■ 42. Section 422.2264 is amended by—

■ a. Adding paragraphs (a)(2)(i)(A) and reserved (a)(2)(i)(B);

■ b. Revising paragraph (b)(2);

■ c. Removing paragraphs (c)(1)(ii)(C) and (E).

■ d. Redesignating paragraph (c)(1)(ii)(D) as paragraph (c)(1)(ii)(C); and

■ e. Revising paragraphs (c)(2)(i), (c)(3)(i), and (c)(3)(iii)(A) and (B).

The additions and revisions read as follows:

§ 422.2264 Beneficiary contact.

* * * * *

(a) * * *

(2) * * *

(i) * * *

(A) Contact is considered to be unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable date and time, was previously scheduled.

(B) [Reserved].

(b) * * *

(2) If the MA organization reaches out to beneficiaries regarding plan business, as outlined in this section, the MA organization must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

* * * * *

(c) * * *

(2) * * *

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.

* * * * *

(3) * * *

(i) At least 48 hours prior to the personal marketing appointment beginning, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

* * * * *

(iii) * * *

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 6 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(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; such Scope of Appointment is valid for six (6) months following the beneficiary's signature date.

* * * * *

■ 43. Section 422.2265 is amended by revising paragraph (b)(4) to read as follows:

§ 422.2265 Websites.

* * * * *

(b) * * *

(4) A provider directory searchable by every element required in the model provider directory, such as name, location, specialty.

* * * * *

■ 44. Section 422.2267 is amended by—

■ a. Redesignating paragraph (a)(3) as paragraph (a)(5);

■ b. Adding new paragraph (a)(3) and paragraph (a)(4);

■ c. Revising paragraph (e)(4) introductory text;

■ d. Adding paragraph (e)(4)(viii);

■ e. Revising paragraphs (e)(5)(ii)(A) introductory text, (e)(10) introductory text, and (e)(12); and

■ f. Revising paragraphs (e)(30)(vi) and (e)(41).

The additions and revisions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(a) * * *

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section or accessible format using auxiliary aids and services upon receiving a request for the materials in another language or accessible format using auxiliary aids and services or when otherwise learning of the enrollee's preferred language or need for an accessible format using auxiliary aids and services. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan, as defined at § 422.2, or applicable integrated plan, as defined at § 422.561, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard in paragraph (a)(2) of this section.

(5) * * *

(e) * * *

(4) *Pre-Enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments, the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

* * * * *

(viii) Effect on current coverage.

(5) * * *

(ii) * * *

(A) Information on the following medical benefits, starting in the top half of the first page and in the order as identified in paragraphs (A)(1) through (A)(10), including—

* * * * *

(10) *Non-renewal Notice.* This is a standardized communications material through which plans must provide the information required under § 422.506.

* * * * *

(12) *Provider Termination Notice.* This is a model communications material through which plans must provide the information required under § 422.111(e).

(i) The written Provider Termination Notice must be provided in hard copy via U.S. mail (first class postage is recommended, but not required).

(ii) The written Provider Termination Notice must do all of the following:

(A) Inform the enrollee that the provider will no longer be in the network and the date the provider will leave the network.

(B) Include names and phone numbers of in-network providers that the enrollee may access for continued care (this information may be supplemented with information for accessing a current provider directory, including both online and direct mail options).

(C) Explain how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider.

(D) Provide information about the annual coordinated election period and the MA open enrollment period, as well as explain that an enrollee who is impacted by the provider termination may contact 1–800–MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period, as specified in § 422.62(b)(26), based on the individual's unique circumstances and consistent with existing parameters for this SEP.

(E) Include the MA organization's call center telephone number, TTY number, and hours and days of operation.

(iii) The telephonic Provider Termination Notice specified in § 422.111(e)(1)(i) must relay the same information as the written Provider Termination Notice as described in paragraph (e)(12)(ii) of this section.

* * * * *

(30) * * *

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section; and

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all MA organizations in the service area the disclaimer consists of the statement: ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area which are plans offered by [insert list of MA organizations here]. Please contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program to get information on all of your options.'' If the TPMO sells for all MA organizations in the service area the disclaimer consists of the statement: ''We offer the following plans in your area [insert list of MA organizations]. You can always contact *Medicare.gov*, 1–800–MEDICARE, or your local State

Health Insurance Program for help with plan choices.'' The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

■ 45. Section 422.2272 is amended by adding paragraph (e) to read as follows:

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

■ 46. Section 422.2274 is amended by adding paragraph (c)(12), revising paragraph (g)(2)(ii), and adding paragraph (g)(4) to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(12) Ensure that, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs.

* * * * *

(g) * * *

(2) * * *

(ii) Record all marketing, sales, and enrollment calls, including calls via web-based technology, in their entirety.

* * * * *

(4) Personal beneficiary data collected by a TPMO may not be distributed to other TPMOs.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 47. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 48. Section 423.4 is amended by adding in alphabetical definitions for ''Authorized generic drug'', ''Biological product'', ''Brand name biological product'', ''Immediate need individual'', ''Interchangeable biological product'', ''Limited Income Newly Eligible Transition (LI NET) sponsor'', ''MTM program'', ''Reference biological product'', and ''Unbranded biological product'' to read as follows:

§ 423.4 Definitions.

* * * * *

Authorized generic drug means a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)).

Biological product means a product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

Brand name biological product means a product licensed under section 351(a) or 351(k) of the Public Health Service Act and marketed under a brand name.

* * * * *

Immediate need individual means a beneficiary whose enrollment into LI NET is on the basis of presumed low income subsidy eligibility and immediate need of a Part D drug.

* * * * *

Interchangeable biological product means a product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that FDA has determined to be interchangeable with a reference product in accordance with sections 351(i)(3) and 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(i)(3) and 262(k)(4)).

Limited Income Newly Eligible Transition (LI NET) sponsor means a Part D sponsor selected by CMS to administer the LI NET program.

* * * * *

MTM program means a medication therapy management program described at § 423.153(d).

* * * * *

Reference biological product means a product as defined in section 351(i)(4) of the Public Health Service Act (42 U.S.C. 262(i)(4)).

* * * * *

Unbranded biological product means a product licensed under a biologics license application (BLA) under section 351(a) or 351(k) of the Public Health Service Act (42 U.S.C. 262(a) or 262(k)) and marketed without a brand name. It is licensed under the same BLA as the corresponding brand name biological product.

■ 49. Section 423.32 is amended by adding paragraphs (h) and (i) to read as follows:

§ 423.32 Enrollment process.

* * * * *

(h) *Notification of reinstatement based on beneficiary cancellation of new enrollment.* When an individual is disenrolled from a Part D plan due to the election of a new plan, the Part D plan sponsor must reinstate enrollment if the individual cancels the election in the new plan timeframes established by CMS. The Part D plan sponsor offering the plan from which the individual was disenrolled must send the member notification of the reinstatement within 10 calendar days of receiving confirmation of the individual's reinstatement.

(i) *Exception for employer group health plans.* (1) In cases when a PDP sponsor has both a Medicare contract and a contract with an employer, and in which the PDP sponsor arranges for the employer to process election forms for Part D eligible group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 423.343(a), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (i)(1) of this section, the beneficiary must certify that, at the time of enrollment in the PDP, he or she received the disclosure statement specified in § 423.128.

(3) Upon receipt of the election from the employer, the PDP sponsor must submit the enrollment to CMS within timeframes specified by CMS.

■ 50. Section 423.36 is amended by adding paragraphs (b)(4), (d), (e), and (f) to read as follows:

§ 423.36 Disenrollment process.

* * * * *

(b) * * *

(4) In the case of an incomplete disenrollment request—

(i) Document its efforts to obtain information to complete the disenrollment request;

(ii) Notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request.

(iii) The organization must deny the request if any additional information needed to make the disenrollment request ''complete'' is not received within the following timeframes:

(A) For disenrollment requests received during the AEP by December 7,

or within 21 calendar days of the request for additional information, whichever is later; and

(B) For disenrollment requests received during all other election periods, by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.

* * * * *

(d) *Incomplete disenrollment.* A disenrollment request is considered to be incomplete if the required but missing information is not received by the PDP sponsor within the timeframe specified in paragraph (b)(4)(iii) of this section.

(e) *Exception for employer group health plans.* (1) In cases when a PDP sponsor has both a Medicare contract and a contract with an employer, and in which the PDP sponsor arranges for the employer to process election forms for Part D eligible group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 423.343(a), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election from the employer, the PDP sponsor must submit the disenrollment to CMS within timeframes specified by CMS.

(f) *Effect of failure to submit disenrollment notice to CMS promptly.* If the PDP sponsor fails to submit the correct and complete notice required in paragraph (c)(1) of this section, the PDP sponsor must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

■ 51. Section 423.38 is amended by—

■ a. Revising paragraphs (c)(7), (16), and (23).

■ b. Redesignating paragraph (c)(34) as paragraph (c)(35); and

■ c. Adding new paragraph (c)(34).

The revisions and addition read as follows:

§ 423.38 Enrollment periods

* * * * *

(c) * * *

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered. Also eligible for this SEP are individuals who, as a result of a change in permanent residence, have new Part D plan options available to them.

* * * * *

(16) The individual who is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B that starts January 1, 2023, is eligible to request enrollment in a Part D plan. The special enrollment period begins when the individual submits their Part B application and continues for the first 2 months of Part B enrollment. The Part D plan enrollment is effective the first of the month following the month the Part D sponsor receives the enrollment request.

* * * * *

(23) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for a SEP to make a Part D enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. The SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, the date the incident automatically ends under applicable State or local law, or, if the incident end date is not otherwise identified, the incident end date specified in paragraph (c)(23)(i) of this section.

(i) If the incident end date of an emergency or major disaster is not otherwise identified, the incident end date will be 1 year after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration, whichever is later. Therefore, the maximum length of this SEP, if the incident end date is not otherwise identified, is 14 full calendar months after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration.

(ii) The individual is eligible for this SEP provided the individual—

(A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (c)(23), in an area for which a Federal, State or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area; and

(C) Was eligible for another election period at the time of the SEP eligibility period described in this paragraph (c)(23); and

(D) Did not make an election during that other election period due to the emergency or major disaster.

* * * * *

(34) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR parts 406.27 and 407.23. The SEP begins when the individual submits their premium-Part A or Part B application and continues for the first 2 months of enrollment in premium Part A or Part B. The Part D plan enrollment is effective the first of the month following the month the Part D plan receives the enrollment request.

* * * * *

■ 52. Section 423.44 is amended by—

■ a. Adding paragraph (b)(1)(iii);

■ b. Revising paragraphs (d)(1) introductory text, (d)(1)(iii)(A), and (d)(1)(v) and (vi);

■ c. Revising paragraphs (d)(2)(iii) and (iv);

■ d. Adding paragraph (d)(2)(viii);

■ e. Revising paragraphs (d)(5)(i) and (ii); and

■ f. Adding paragraph (d)(9).

The additions and revisions read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(b) * * *

(1) * * *

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(9) of this section.

* * * * *

(d) * * *

(1) Except as specified in paragraph (d)(1)(v) of this section, a PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

* * * * *

(iii) * * *

(A) Be at least 2 whole calendar months; and

* * * * *

(v) A PDP sponsor may not disenroll an individual who had monthly premiums withheld per § 423.293(a) and (e) of this part or who is in premium withhold status, as defined by CMS. In addition, sponsors may not disenroll a member or initiate the disenrollment process if the sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer.

(vi) When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as a Part D sponsor) may reinstate enrollment in the PDP, without interruption of coverage, if the

individual submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date, has not previously requested reinstatement for good cause during the same 60 day period following the involuntary disenrollment, shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(2) * * *

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimer's disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures, through the notices described in paragraph (d)(2)(viii) of this section. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS. Dated copies of the notices required in paragraph (d)(2)(viii) of this section must also be submitted to CMS.

* * * * *

(viii) *Required notices.* The PDP sponsor must provide the individual two notices prior to submitting the request for disenrollment to CMS. The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action. If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the sponsor must begin the process again. The sponsor must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-day period the individual has the opportunity to cease their behavior. The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the PDP sponsor will request CMS permission to involuntarily disenroll the member. This notice must be provided prior to submission of the request to CMS. These notices are in addition to the disenrollment submission notice required under § 423.44(c).

* * * * *

(5) * * *

(i) The PDP must disenroll an individual, and must document the basis for such action, if the PDP establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved out of the PDP service area and must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area.

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been determined by the PDP sponsor to be absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan, and document the basis for such action, effective on the first day of the 13th month after the individual left the service area and must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within the first ten calendar days of the twelfth month of an individual's temporary absence from the plan service area or, if the sponsor learns of the individual's temporary absence from the plan service area after the expiration of the 12 month period, within 10 calendar days of the sponsor learning of the absence. The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 423.2267(e), if provided by mail, is returned to the Part D plan sponsor by the US Postal Service as undeliverable and a forwarding address is not provided.

* * * * *

(9) *Individual commits fraud or permits abuse of enrollment card*—(i) *Basis for disenrollment.* A PDP may disenroll the individual from a Part D plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the PDP; or

(B) Intentionally permits others to use his or her enrollment card to obtain drugs under the PDP

(ii) *Notice of disenrollment.* The Part D plan must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS.* The Part D plan must report to CMS any disenrollment based on fraud or abuse by the individual.

* * * * *

■ 53. Section 423.100 is amended by:

■ a. Revising the definition for ''Affected enrollee''; and

■ b. Adding, in alphabetical order, definitions for ''Corresponding drug''; ''Formulary crosswalk''; ''Immediate negative formulary change''; ''Maintenance change''; ''Negative formulary change''; ''Non-maintenance change''; ''Other specified entities''; and ''Safety-based claim edit''.

The revision and addtions read as follows:

§ 423.100 Definitions.

* * * * *

Affected enrollee, as used in this subpart, means a Part D enrollee who is currently taking a covered Part D drug that is subject to a negative formulary change that affects the Part D enrollee's access to the drug during the current plan year.

* * * * *

Corresponding drug means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference biological product, or an unbranded biological product of a biological product.

* * * * *

Formulary crosswalk means the process during bid submission by which a formulary (as defined at § 423.4) is assigned to one or more Part D plans with single- or multi-tier benefit structures.

* * * * *

Immediate negative formulary change means an immediate substitution or market withdrawal that meets the requirements of § 423.120(e)(2)(i) or (ii) respectively.

* * * * *

Maintenance change means the following negative formulary changes:

(1) making any negative formulary changes to a drug and at the same time

adding a corresponding drug at the same or lower cost-sharing tier and with the same or less restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements (other than immediate substitutions that meet the requirements of § 423.120(e)(2)(i));

(2) Removing a non-Part D drug;

(3) Adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning;

(4) Removing a drug deemed unsafe by FDA or withdrawn from sale by the manufacturer if the Part sponsor chooses not to treat it as an immediate negative formulary change;

(5) Removing a drug based on long-term shortage and market availability;

(6) Making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization; or

(7) Adding PA to help determine Part B versus Part D coverage.

Negative formulary change means the following changes with respect to a covered Part D drug: removing a drug from a formulary; moving a drug to a higher cost-sharing tier; or 3) adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements. Negative formulary changes do not include safety-based claim edits which are not submitted to CMS as part of the formulary.

* * * * *

Non-maintenance change means a negative formulary change that is not a maintenance change or an immediate negative formulary change.

* * * * *

Other specified entities means State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists.

* * * * *

Safety-based claim edit means a claim edit consistent with drug utilization review (DUR) requirements described at § 423.153(c)(2).

* * * * *

§ 423.104 [Amended]

■ 54. Section 423.104 is amended in paragraph (d)(2)(iv)(A)(*6*) by:

■ a. Removing the phrase ''subparagraph (d)(2)(iv)(A)(*2*)'' and adding its place the phrase ''paragraph (d)(2)(iv)(A)(*2*) of this section; and

■ b. Removing the phrase ''subject to the requirements at § 423.120(b)'' and adding in its place the phrase ''subject to the requirements at §§ 423.120(b), (e), and (f)''.

■ 55. Section 423.120 is amended by—

■ a. Revising paragraph (b)(3) introductory text;

■ b. Adding (b)(3)(i)(A)(*5*);

■ c. Revising paragraphs (b)(3)(i)(B) and (b)(3)(iii) and (iv);

■ d. Adding paragraphs (b)(3)(vii) and (viii);

■ e. Revising paragraphs (b)(5) and (6); and

■ f. Adding paragraphs (b)(8) and (9);

■ g. Revising the paragraph (c) subject heading; and

■ h. Adding paragraphs (c)(7) and (e) through (g).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(3) *Transition process.* A Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary, including Part D drugs that are on a sponsor's formulary, but require prior authorization, step therapy, or under a plan's drug utilization management rules, are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100. The transition process must:

(i) * * *

(A) * * *

(*5*) Current enrollees experiencing a level of care change, if the sponsor is notified of such change by the enrollee or their representative, their prescriber, the hospital or facility, or a pharmacy before or at the time of the request for the fill referenced in § 423.120(b)(3)(iii).

* * * * *

(B) Not apply in cases of immediate changes as permitted under paragraph (e)(2) of this section.

* * * * *

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug (including Part D drugs that are on a plan's formulary but under a plan's utilization management rules require prior authorization, step therapy, or are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100 during the time period specified in paragraph (b)(3)(ii) of this section by providing a one-time, temporary supply of at least an approved month's supply of medication, unless the prescription is written by a prescriber for less than an approved month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of an approved month's supply of medication.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill, counting the end of the first business day after adjudication as the end of business day 1. For long-term care residents dispensed multiple supplies of a Part D drug, in increments of 14-days-or-less, consistent with the requirements under § 423.154, the written notice must be provided within 3 business days after adjudication of the first temporary fill.

* * * * *

(vii)(A) If a Part D sponsor has access prior drug claims history for an enrollee (through an affiliated plan or otherwise), the sponsor must use a minimum 108-day claims history lookback period to determine whether a pharmacy claim represents a new prescription which does not require a transition fill or ongoing drug therapy which requires a transition fill.

(B) If a Part D sponsor does not have access to prior claims history for the enrollee and cannot determine at point-of-sale whether a pharmacy claim represents a new prescription or ongoing therapy, the sponsor must treat the prescription as ongoing therapy which requires a transition fill.

(viii) A sponsor's transition policies and procedures must include assurances that the Part D sponsor's Pharmacy & Therapeutics Committee has reviewed, provided recommendations as warranted, and approved the plan's transition policies and procedures to comply with this paragraph (b)(3) and any applicable requirement under subpart M. Such policies and procedures must be submitted through a process specified by CMS as part of the plan's annual bid.

* * * * *

(5) *Notice of formulary changes.* Part D sponsors must provide notice of changes to CMS-approved formularies as specified in § 423.120(f). Paragraph (e)(2)(i) of this section is the successor regulation to paragraph (b)(5)(iv) of this section for purposes of section 1860D–4(b)(3)(I)(ii) of the Act .

(6) *Changes to CMS-approved formularies.* Changes to CMS-approved formularies may be made only in accordance with paragraph (e) of this section.

* * * * *

(8) *Emergency supplies.* A Part D sponsor must cover an emergency supply of a non-formulary Part D drug for a long-term care facility resident after any applicable transition period under paragraph (b)(3) of this section, including Part D drugs that are on a sponsor's formulary but require prior

authorization, step therapy, or are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100. An emergency supply must be for at least 31 days of medication, regardless of dispensing increments, unless the prescription is written by a prescriber for less than 31 days.

(9) *Single-tier benefit requirement for defined standard coverage.* A Part D plan offering Defined Standard coverage may not apply multi-tier benefit structures to the formulary (as defined in § 423.4) to which it has been assigned via the formulary crosswalk (as defined in § 423.100). The formulary for such Part D plan must be assigned to a single-tier benefit structure, except when such formulary has also been assigned to one or more other Part D plans that use multi-tier benefit structures. When a formulary has been assigned to a Part D plan offering Defined Standard coverage and to one or more other Part D plans with multi-tier benefit structures, such multi-tier benefit structures do not apply to the plan offering Defined Standard coverage.

* * * * *

(c) *Use of standardized technology and identifiers.*

* * * * *

(7)(i) A Part D sponsor must attempt to confirm the validity of a prescriber Drug Enforcement Administration (DEA) registration number for a pharmacy claim for a Part D drug that is a Schedule II, III, IV or V drug, and if and that if the DEA registration number is not on the claim, the sponsor must cross-reference the prescriber's Type 1 National Provider Identifier (NPI) on the claim to any associated individual prescriber DEA number.

(ii) If the DEA registration number is not valid or active, or does not have an associated Schedule that is consistent with the drug for which a claim was submitted, the Part D sponsor must:

(A) Reject the claim, and

(B) Provide the pharmacy with the electronic reason code when rejecting the claim.

(iii) If the pharmacy confirms the validity of the DEA registration number via electronic override code, or the sponsor is not able to cross-reference the Type 1 NPI to a prescriber DEA registration number, the sponsor must process the claim under the applicable benefit plan rules.

(iv) With respect to written member requests for reimbursement, the Part D sponsor must determine whether the DEA registration number of the prescriber was valid and active for the date of service, and if the DEA registration number had an associated Schedule that was consistent with the drug for which the member request for reimbursement was submitted for the date of service. If the DEA number was not valid or active, or there was not an associated Schedule that was consistent with the drug, the Part D sponsor must:

(A) Deny the member request for reimbursement, and

(B) Provide the beneficiary with a written notice consistent with § 423.568(g).

* * * * *

(e) *Approval of changes to CMS-approved formularies.* A Part D sponsor may not make any negative formulary changes to its CMS-approved formulary except as specified in this section.

(1) *Negative change request.* Except as provided in paragraph (e)(2) of this section, prior to implementing a negative formulary change, Part D sponsors must submit to CMS, at a time and in a form and manner specified by CMS, a negative formulary change request.

(2) *Exception for immediate negative formulary changes,* A negative change request is not required in the following circumstances:

(i) *Immediate substitutions.* A Part D sponsor may immediately make negative formulary changes to a brand name drug, a reference biological product, or a brand name biological product provided that at the same time, it adds a corresponding drug to its formulary on the same or lower cost-sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section because such drug was not yet available on the market, and the Part D sponsor has provided advance general notice as specified in paragraph (f)(2) of this section.

(ii) *Market withdrawals.* A Part D sponsor may immediately remove from its formulary any Part D drugs deemed unsafe by the Food and Drug Administration (FDA) or withdrawn from sale by their manufacturer.

(3) *Approval process for negative formulary changes*—(i) *Maintenance changes.* Negative change requests for maintenance changes are deemed approved 30 days after submission unless CMS notifies the Part D sponsor otherwise.

(ii) *Non-maintenance changes.* Part D sponsors must not implement non-maintenance changes until they receive notice of approval from CMS. Affected enrollees are exempt from non-maintenance changes for the remainder of the contract year.

(4) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided in paragraph (e)(2) of this section, a Part D sponsor may not make a negative formulary change that takes effect between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(f) *Provision of notice regarding changes to CMS-approved formularies*—(1) *Notice of negative formulary changes:* Except as specified in paragraphs (f)(2) and (3) of this section, prior to making any negative formulary change, a Part D sponsor must provide notice to CMS and other specified entities at least 30 days prior to the date such change becomes effective, and must either: provide written notice to affected enrollees at least 30 days prior to the date the change becomes effective, or when an affected enrollee requests a refill of the Part D drug, provide such enrollee with an approved month's supply of the Part D drug under the same terms as previously allowed and written notice of the formulary change. The requirement to provide notice to CMS is satisfied upon a Part D sponsor's submission of a negative change request described in paragraph (e) of this section. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2).

(2) *Advance general notice of immediate negative formulary changes.* In the case of immediate negative formulary changes described in paragraph (e)(2) of this section, a Part D sponsor must provide advance general notice to all current and prospective enrollees and other specified entities in its formulary and other applicable beneficiary communication materials advising that the Part D sponsor may make immediate negative formulary changes consistent with the requirements of paragraph (e)(2) at any time. Such advance general notice must include information about how to access the plan's online formulary; how to contact the plan; and that written notice of any change made will describe the specific drugs involved. Advance general notice of immediate substitutions must also specify that the written notice will contain information on the steps that enrollees may take to request coverage determinations and exceptions. Advance general notice of immediate substitutions is provided to

CMS during bid submission. Advance general notice of market withdrawals is provided to CMS in the advance notice of immediate negative formulary changes that Part D sponsors provide to enrollees and other specified entities required earlier in this paragraph (f)(2).

(3) *Retrospective notice and update.* In the case of a negative formulary change described in paragraph (e)(2) of this section, the Part D sponsor must provide notice to other specified entities and written notice to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2). Part D sponsors also must submit such changes to CMS, in a form and manner specified by CMS, in their next required or scheduled formulary update.

(4) *Content of written notice:* Any written notice required under this paragraph (other than advance general notice) must contain the following information—

(i) The name of the affected covered Part D drug;

(ii) Whether the plan is removing the covered Part D drug from the formulary, moving it to a higher cost-sharing tier, or adding or making more restrictive PA, ST, or QL requirements;

(iii) The reason for the negative formulary change;

(iv) Appropriate alternative drugs in the same or a lower cost-sharing tier and the expected cost-sharing for those drugs; and

(v) For formulary changes other than those described in paragraph (e)(2)(B) of this section, the means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578.

(5) *Notice of other formulary changes.* Part D sponsors provide appropriate notice of all formulary changes other than negative formulary changes by (A) providing advance general notice to all current and prospective enrollees, CMS, and other specified entities in formulary and other applicable beneficiary communication materials advising them that the Part D sponsor may make formulary changes other than negative formulary changes at any time and providing information about how to access the plan's online formulary and how to contact the plan; and (B) providing notice of specific formulary changes to other specified entities by complying with § 423.128(d)(2) and to CMS by submitting such changes to CMS in their next required or scheduled formulary update.

(g) *Drug shortages.* For the purpose of this section, a drug or biological product is subject to a shortage if it is on the U.S. Food and Drug Administration drug shortages list. With respect to a product on a Part D plan's formulary that is subject to a shortage, a Part D sponsor must—

(1) For at least the duration of the shortage, permit enrollees affected by the shortage to obtain coverage of—

(i) A therapeutically equivalent non-formulary drug or interchangeable biological product, if any, without requiring enrollees affected by the shortage to meet formulary exception requirements at § 423.578(b); or

(ii) A therapeutically equivalent formulary drug or interchangeable biological product, if any, that requires prior authorization or step therapy without requiring enrollees affected by the shortage to meet prior authorization or step therapy requirements.

(2) Part D sponsors may charge the applicable cost sharing based on the therapeutically equivalent drug's or interchangeable biological product's formulary status and plan benefit design for claims submitted consistent with paragraph (g)(1)(i) or (ii) of this section.

■ 56. Section 423.128 is amended by revising paragraphs (d)(1)(iii)(A), (d)(1)(v)(B), (d)(2)(iii), and (e)(6) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(d) * * *

(1) * * *

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals. Such interpreters must:

(*1*) Adhere to generally accepted interpreter ethics principles, including confidentiality;

(*2*) Demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and

(*3*) Interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

* * * * *

(v) * * *

(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

* * * * *

(2) * * *

(iii) Provides current and prospective Part D enrollees with notice that is timely under § 423.120(f) regarding any negative formulary changes on its Part D plan's formulary.

* * * * *

(e) * * *

(6) Include any negative formulary changes applicable to an enrollee for which Part D plans are required to provide notice as described in § 423.120(f).

* * * * *

§ 423.150 [Amended]

■ 57. Section 423.150 is amended in paragraph (a) by removing the phrase ''medication therapy management programs (MTMP)'' and adding in its place ''MTM programs''.

■ 58. Section 423.153 is amended by:

■ a. Revising the section heading;

■ b. Removing the paragraph (d) subject heading;

■ c. Removing the phrase ''MTMP'' and adding in its place the phrase ''MTM program'' in paragraph (d)(1) introductory text;

■ d. Revising paragraphs (d)(1)(vii)(B)(*1*)(*i*) and (d)(1)(vii)(B)(*2*),

■ e. Removing the phrase ''MTMP'' and adding in its place the phrase ''MTM program'' in paragraph (d)(2) introductory text;

■ f. Revising paragraphs (d)(2)(i)(B) and (C);

■ g. Adding paragraphs (d)(2)(iii) and (iv);

■ h. Removing the phrase ''MTMP'' and adding in its place the phrase ''MTM program'' in paragraphs (d)(3) and (4);

■ i. Revising paragraph (d)(5)(i) and (ii); and

■ j. Removing the phrase ''MTMP'' and adding in its place the phrase ''MTM program'' in paragraph (d)(6);

The revisions and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, MTM programs, drug management programs, and access to Medicare Parts A and B claims data extracts.

* * * * *

(d) *MTM program.*

(1) * * *

(vii) * * *

(B) * * *

(*1*) * * *

(*i*) Must include an interactive consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth; and

* * * * *

(*2*) If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate due to cognitive impairment, the pharmacist or other qualified provider may perform the

comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.

* * * * *

(2) * * *

(i) * * *

(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 for a plan year starting before January 1, 2024, and five Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment for a plan year starting on or after January 1, 2024; and

(C) Are likely to incur annual covered Part D drug costs greater than or equal to the MTM cost threshold determined by CMS, as specified in this paragraph (d)(2)(i)(C).

(*1*) For 2011, the MTM cost threshold is set at $3,000.

(*2*) For 2012 through 2023, the MTM cost threshold is set at $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv).

(*3*) Beginning January 1, 2024, the MTM cost threshold is set at the average annual cost of five generic drugs, as defined at § 423.4, as determined using the PDE data specified at § 423.104(d)(2)(iv)(C).

* * * * *

(iii) Beginning January 1, 2024, in identifying beneficiaries who have multiple chronic diseases under paragraph (d)(2)(i)(A) of this section, Part D plan sponsors must include all of the following diseases, and may include additional chronic diseases:

(A) Alzheimer's disease;

(B) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis);

(C) Chronic congestive heart failure (CHF);

(D) Diabetes;

(E) Dyslipidemia;

(F) End-stage renal disease (ESRD);

(G) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS);

(H) Hypertension;

(I) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions); and

(J) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders).

(iv) Beginning January 1, 2024, in identifying the number of Part D drugs under paragraph (d)(2)(i)(B) of this section, Part D plan sponsors must include all maintenance drugs, relying on information in a widely accepted, commercially or publicly available drug database to make such determinations.

* * * * *

(5) * * *

(i) Describe in its application how it takes into account the resources used and time required to implement the MTM program it chooses to adopt in establishing fees for pharmacists or others providing MTM services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

* * * * *

■ 59. Section 423.154 is amended by revising paragraph (c) to read as follows:

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans

* * * * *

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section, except paragraphs (a)(2) and (3), for pharmacies when they service intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

* * * * *

■ 60. Section 423.160 is amended by—

■ a. Revising paragraphs (b)(1)(i) through (v);

■ b. Adding paragraphs (b)(1)(vi) and (vii);

■ c. Adding paragraphs (b)(2)(v) and (b)(3)(iii);

■ d. Revising paragraph (b)(4)(ii);

■ e. Adding paragraphs (b)(4)(iii), (b)(7)(i), and a reserved (b)(7)(ii);

■ f. Revising paragraph (b)(8)(ii); and

■ g. Adding paragraph (b)(8)(iii).

The revisions read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(1) * * *

(i) Prior to April 1, 2009, the standards specified in paragraphs (b)(2)(i), (b)(3)(i) and (ii), (b)(4), (b)(5)(i), and (b)(6).

(ii) On or after April 1, 2009, to February 7, 2014, the standards specified in paragraphs (b)(2)(ii), (b)(3)(i) and (ii), (b)(4), (b)(5)(i) and (b)(6).

(iii) From February 8, 2014, until February 28, 2015, the standards specified in paragraphs (b)(2)(ii), (b)(3)(i) and (ii), (b)(4), (b)(5)(ii), and (b)(6).

(iv) From March 1, 2015 until December 31, 2019, the standards specified in paragraphs (b)(2)(iii), (b)(3)(i) and (ii), (b)(4)(i), (b)(5)(iii), and (b)(6).

(v) From January 1, 2020 until June 30, 2023, the standards specified in paragraphs (b)(2)(iv) and (b)(3)(i) and (ii), (b)(4)(ii), (b)(5)(iii), and (b)(6) of this section.

(vi) Beginning July 1, 2023, the standards required by paragraphs (b)(2)(v), (b)(3)(iii), (b)(4)(iii), (b)(5)(iii), and (b)(6) of this section.

(vii) Beginning January 1, 2025, the standard specified in paragraph (b)(7)(i) of this section.

* * * * *

(2) * * *

(v) Communication of a prescription or related prescription-related information between prescribers and dispensers or between dispensers must comply with 45 CFR 170.205(b) for the business functions supported by the following transactions:

(A) GetMessage.

(B) Status.

(C) Error.

(D) NewRxRequest.

(E) NewRx.

(F) RxChangeRequest.

(G) RxChangeResponse.

(H) RxRenewalRequest.

(I) Resupply.

(J) RxRenewalResponse.

(K) Verify.

(L) CancelRx.

(M) CancelRxResponse.

(N) RxFill.

(O) DrugAdministration.

(P) NewRxResponseDenied.

(Q) RxTransferInitiationRequest.

(R) RxTransfer.

(S) RxTransferConfirm.

(T) RxFillIndicatorChange.

(U) Recertification.

(V) REMSIinitiationRequest.

(W) REMSIinitiationResponse.

(X) REMSRequest.

(Y) REMSResponse.

* * * * *

(3) * * *

(iii) Eligibility inquiries and responses between the Part D sponsor and prescribers and between the Part D sponsor and dispensers must comply with 45 CFR 162.1202.

(4) * * *

(ii) From January 1, 2020, until June 30, 2023 the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section).

(iii) Beginning July 1, 2023, comply with 45 CFR 170.205(b).

* * * * *

(7) * * *

(i) Beginning January 1, 2025, Part D sponsors' RTBT must comply with 45 CFR 170.205(c).

(ii) [Reserved]

(8) * * *

(ii) From January 1, 2022 until June 30, 2023, Part D sponsors and prescribers must use the standard specified in paragraph (b)(8)(i) of this section for the transactions listed in paragraphs (b)(8)(i)(A) through (D) of this section.

(iii) Beginning July 1, 2023, Part D sponsors and prescribers must comply with 45 CFR 170.205(b) for the business functions supported by the following applicable transactions:

(A) PAInitiationRequest.

(B) PAInitiationResponse.

(C) PARequest.

(D) PAResponse.

(E) PAAppealRequest.

(F) PAAppealResponse.

(G) PACancelRequest.

(H) PACancelResponse.

(I) PANotification.

* * * * *

§ 423.165 [Amended]

■ 15. Section 423.165 is amended in paragraph (b)(2) by removing the phrase ''MTMPs'' and adding the phrase ''MTM programs'' in its place.

■ 61. Section 423.182 is amended by in paragraph (a) by adding in alphabetical order a definition for ''health equity index'' and revising paragraphs (b)(1) and (b)(3)(ii)(A)(*1*) to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

* * * * *

(b) * * *

(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract and a Part D summary rating for each PDP contract using the 5-star rating system described in this subpart. For PDP contracts, the Part D summary rating is the highest rating. Measures are assigned stars at the contract level and weighted in accordance with § 423.186(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 423.186(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 423.186(c), with both the reward factor and CAI applied as applicable, as described in § 423.186(f). Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 423.186(d) with both the reward factor and CAI applied as applicable, as described in § 423.186(f). CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

* * * * *

(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, call center measures, and improvement measures. The survey-based measures will 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. The Part C and D improvement measures are not calculated for first year consolidations.

* * * * *

■ 62. Section 423.184 is amended by revising paragraph (d)(1)(v) and adding paragraph (e)(1)(iii) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(d) * * *

(1) * * *

(v) Add alternative data sources or expand modes of data collection.

* * * * *

(e) * * *

(1) * * *

(iii) The measure steward other than CMS retires a measure.

* * * * *

■ 63. Section 423.186 is amended by—

■ a. Revising paragraphs (a)(2)(i), (c)(1), (d)(1), (e)(1)(iii) and (iv), (e)(2), (f)(1) introductory text, and (f)(2)(i) introductory text;

■ b. Adding paragraphs at (f)(3); and

■ c. Revising paragraphs (g)(1), (i)(7)(i), and (i)(8)(i).

The revisions and addition 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. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 through October 2024, CMS will add 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. 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.

* * * * *

(c) * * *

(1) CMS will calculate the Part D summary ratings using the weighted mean of the measure-level Star Ratings for Part D, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(d) * * *

(1) The overall rating for a MA–PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

* * * * *

(2) *Rules for new and substantively updated measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. Substantively updated measures will receive a weight of 1 in their first year returning to the Star Ratings after being on the display page. In subsequent years, the measure will be

assigned the weight associated with its category.

* * * * *

(f) * * *

(1) *Reward factor.* Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

* * * * *

(2) * * *

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

* * * * *

(3) *Health equity index.* Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA–PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA–PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA–PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low income subsidy or being dual eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings would be adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Data are used for contracts that have data for only the most recent of the 2 years, but data are not used for contracts that have data for only the first of the 2 years.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA–PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the health equity index. CMS will announce the measures being evaluated for inclusion in the calculation of the health equity index under this paragraph (f)(3) of this section through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's health equity index, the measure must meet the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each measure for the subset enrollees that have one or more of the specified SRFs will be assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving –1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all measures included in the index using the Star Ratings measure weight for each measure divided by the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale with a contract receiving 0 if the contract receives a score of 0 or less on the health equity index and 0.4 if the contract receives a score of 1 on the health equity index. For contracts that have percentages of enrollees with SRFs

greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.2 if the contract receives a score of 1 on the health equity index. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have a health equity index score calculated (that is, contracts that are not scored on at least half of the measures included in the index) would not receive a HEI reward.

(ix) The HEI reward is added to the overall rating, Part C rating for MA–PDs and MA-only contracts (and cost contracts), Part D rating for MA–PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

(g) * * *

(1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA–PD contracts and Part D summary rating for PDPs), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) If the highest rating for each contract-type is 5 stars without the use of the improvement measure(s) and with the reward factor adjustment if applicable and the CAI adjustment under paragraph (f) of this section, a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating is less than 5 stars without the use of the improvement measure(s) and with the reward factor adjustment if applicable and CAI adjustment, the rating will be calculated with the improvement measure(s).

* * * * *

(i) * * *

(7) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

* * * * *

(8) * * *

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

* * * * *

■ 64. Section 423.265 is amended by

■ a. Redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4), respectively;

■ b. Adding paragraph heading to the newly redesignated paragraph (b)(4); and

■ c. Adding new paragraph (b)(2) and paragraph (b)(5).

The additions read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Substantial differences between bids*—(i) *General rule.* Except as provided in paragraph (b)(2)(ii) of this section, potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered ''substantially different,'' each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(ii) *Exception.* A potential Part D sponsor's enhanced bid submission does not have to reflect the substantial differences as required in paragraph (b)(2)(i) of this section relative to any of its other enhanced bid submissions.

* * * * *

(4) *Bid acceptance.* * * *

(5) *Limitations on changes.* After a Part D sponsor is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), the Part D sponsor must not change, and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182) for the contract year without modification, except where a modification in benefits is required by law.

* * * * *

■ 65. Section 423.272 is amended by adding paragraph (b)(5) to read as follows:

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

* * * * *

(b) * * *

(5) *Limit on number of PDP contracts held by subsidiaries of the same parent organization in a region*—(i) *General.* Except as provided in paragraphs (b)(5)(ii) and (iii) of this section, CMS does not approve a bid when it would result in a PDP sponsor (or a PDP sponsor's parent organization), directly or through its subsidiaries, offering plan benefit packages under more than one PDP contract in a PDP region.

(ii) *Transition period for PDP sponsors with new acquisitions.* CMS does not approve a bid offered by a PDP sponsor (or a PDP sponsor's parent organization, directly or through a subsidiary) that purchased, otherwise acquired, or merged with another PDP sponsor if, after a transition period of two bid cycles after such purchase, acquisition, or merger, as determined by CMS, such bid approval would result in the PDP sponsor (or the PDP sponsor's parent organization), directly or through its subsidiaries, offering plan benefit packages under more than one PDP contract in a PDP region.

(iii) *Transition period for PDP sponsors offering plans in a region under more than one contract on January 1, 2024.* After a transition period of two bid cycles, as determined by CMS, CMS does not approve a bid offered by a PDP sponsor (or a PDP sponsor's parent organization, directly or through a subsidiary) that offered plan benefit packages in a PDP region under more than one PDP contract if it such bid approval would result in the PDP sponsor (or a PDP sponsor's parent organization), directly or through its subsidiaries, offering plan benefit packages under more than one PDP contract in a PDP region.

(iv) *Limitation on PDP contracts per region not applicable to employer group waiver plans.* Notwithstanding any other provisions of this paragraph, a PDP sponsor may offer a PDP contract in the same region as another contract held by the sponsor or the sponsor's parent organization, directly or through its subsidiaries, if one or both contracts only offer employer group waiver plans in that region.

* * * * *

§ 423.293 [Amended]

■ 66. Section 423.293 is amended in paragraph (a)(4) by removing the phrase ''Medicare Advantage organization'' and adding in its place ''Part D sponsor''.

■ 67. Section 423.294 is added to subpart F to read as follows:

§ 423.294 Failure to collect and incorrect collections of premiums and cost sharing.

(a) *Requirement to collect premiums and cost sharing.* A Part D sponsor violates the uniform benefit provisions at § 423.104(b) if it fails to collect or incorrectly collects applicable cost sharing, or fails to collect or incorrectly collects premiums as required by § 422.262(e) of this chapter:

(1) In accordance with the timing of premium payments; or

(2) At the time a drug is dispensed; or

(3) By billing the enrollee or another appropriate party after the fact.

(b) Refunds of incorrect collections—

(1) *Definitions.* As used in this section the following definitions are applicable:

Amounts incorrectly collected. (A) Means amounts that exceed the monthly Part D enrollee premium limits under § 423.286 or exceed permissible cost-sharing or copayment amounts as specified in § 423.104(d) through (f), whether paid by or on behalf of the enrollee;

(B) Includes amounts collected with respect to an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled; and

(C) Excludes de minimis amounts, as calculated per PDE transaction or per monthly premium billing.

De minimis amounts means an amount per PDE transaction for claims adjustments and per month for premium adjustments that does not exceed the de minimis amount determined for purposes of § 423.34(c)(2).

Other amounts due means amounts due to affected enrollees or others on their behalf (other than de minimis amounts) for covered Part D drugs that were—

(A) Accessed at an out-of-network pharmacy in accordance with the requirements at § 423.124; or

(B) Initially denied but, upon appeal, found to be covered Part D drugs the enrollee was entitled to have provided by the Part D plan.

(2) *General rule.* A Part D sponsor must make a reasonable effort to identify all amounts incorrectly collected and to pay any other amounts due during the timeframe for coordination of benefits as established at § 423.466(b). A Part D sponsor must issue a refund for an identified enrollee overpayment within the timeframe specified at § 423.466(a).

(3) *Refund methods*—(i) *Lump-sum payment.* The Part D sponsor must use lump-sum payments for the following:

(A) Amounts incorrectly collected as cost-sharing.

(B) Other amounts due.

(C) All amounts due if the Part D plan is going out of business or terminating its Part D contract for a prescription drug plan(s).

(ii) *Premium adjustment, lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the Part D sponsor may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(iii) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the Part D sponsor must make the refund in accordance with State law.

(4) *Premium reduction and compliance.* If the Part D sponsor does not issue the refund as required under this section within the timeframe specified at § 423.466(a), CMS will reduce the premium the Part D sponsor is allowed to charge a Part D enrollee by the amounts incorrectly collected or otherwise due. In addition, the Part D plan may receive compliance notices from CMS or, depending on the extent of the non-compliance, be the subject of an intermediate sanction (for example, suspension of marketing and enrollment activities) in accordance with subpart O of this part.

(c) *Collections of cost-sharing and premium amounts*—(1) *General rule.* A Part D sponsor must make a reasonable effort to attempt to collect cost sharing from a beneficiary or to bill cost sharing or premiums to another appropriate party for all amounts other than de minimis amounts.

(2) *Timeframe.* Recovery notices must be processed and issued in accordance with the timeframe specified at § 423.466(a). A Part D sponsor must make a reasonable effort to attempt to collect these amounts during the timeframe for coordination of benefits as established at § 423.466(b).

(3) *Retroactive collection of premiums.* Nothing in this section alters the requirements of § 423.293(a)(4) of this part with respect to retroactive collection of premiums.

■ 68. Section 423.308 is amended by:

■ a. Revising the introductory text and paragraph (1) of the definition of ''Gross covered prescription drug costs''; and

■ b. Adding in alphabetical order a definition for ''Reopening''.

The revisions and addition read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of actual costs (as defined by § 423.100 of this part) paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.

* * * * *

Reopening—(1) *Global reopening* means a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

(2) *Targeted reopening* means a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

* * * * *

■ 69. Section 423.346 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing ''within 4 years'' and adding ''within 6 years'' in its place in paragraph (a)(2); and

■ c. Adding paragraphs (e) through (g).

The revision and additions read as follows:

§ 423.346 Reopening.

(a) CMS may conduct a global or targeted reopening to reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) or the Coverage Gap Discount Reconciliation (as described at § 423.2320(b))—

* * * * *

(e) CMS will notify the sponsor(s) that will be included in the reopening of its intention to conduct a global or targeted

reopening when it is necessary for the sponsor(s) to submit prescription drug event (PDE) data and/or direct and indirect remuneration (DIR) for the reopening. The notification to sponsor(s) will include the following:

(1) The date by which PDE and/or DIR data must be accepted by CMS to be included in the reopening, which will be at least 90 calendar days after the date of the notification, and

(2) A statement indicating the Part D contracts or types of contracts that will be included in the reopening.

(f) CMS will announce when it has completed a reopening and provide the sponsor(s) with the following information:

(1) A description of the data used in the reopening,

(2) A statement indicating the Part D contracts or types of contracts that were included in the reopening,

(3) The date by which reports describing the reopening results will be available to the sponsor, and

(4) The date by which a sponsor must submit an appeal, pursuant to § 423.350, if the sponsor disagrees with the reopening results.

(g) Inclusion criteria:

(1) For a global reopening, CMS includes only those Part D sponsor contracts that were in effect for the contract year being reopened and for whom CMS has not sent the final settlement ''Notice of final settlement,'' as described at § 423.521(a), as of the date CMS announces the completion of the reopening pursuant to paragraph (f) of this section.

(2) For a target reopening, CMS includes only Part D sponsor contracts that meet the criteria for inclusion in a global reopening as specified in paragraph (1) of this section and that CMS specifies for inclusion in the reopening as provided in paragraph (e)(2) or (f)(2) of this section.

■ 70. Section 423.360 is amended by revising paragraph (c) to read as follows:

§ 423.360 Reporting and returning of overpayments.

* * * * *

(c) *Identified overpayment.* The Part D sponsor has identified an overpayment when the Part D sponsor knowingly receives or retains an overpayment. The term ''knowingly'' has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

* * * * *

■ 71. Section 423.501 is amended by adding in alphabetical order definitions for ''Final settlement amount'', ''Final settlement process'', and ''Final settlement adjustment period'' to read as follows:

§ 423.501 Definitions.

* * * * *

Final settlement amount is the final payment amount that CMS owes and ultimately pays to a Part D sponsor, or that a Part D sponsor owes and ultimately pays to CMS, with respect to a Part D contract that has consolidated, non-renewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation, as applicable (described in § 422.310);

(2) Part D annual reconciliation (described in § 423.343);

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320) and;

(4) MLR remittances (described in §§ 422.2470 and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS calculates the final settlement amount, issues the final settlement amount along with supporting documentation in the notice of final settlement to the Part D sponsor, receives responses from the Part D sponsor requesting an appeal of the final settlement amount, and takes final actions to adjudicate an appeal (if requested) and make payments to or receive payments from the Part D sponsor. The final settlement amount will be calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

Final settlement adjustment period means the period of time between when the contract terminates and the date the Part D sponsor is issued a notice of the final settlement amount.

* * * * *

■ 72. Section 423.503 is amended by adding paragraph (a)(4) to read as follows:

§ 423.503 Evaluation and determination procedures.

(a) * * *

(4)(i) CMS does not evaluate or issue a notice of determination described in paragraph (c) of this section when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 423.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

* * * * *

■ 73. Section 423.505 is amended by revising paragraph (b)(22), adding paragraph (b)(28), and adding paragraph (i)(6) 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 Part D sponsor.

* * * * *

(28) Require network pharmacies that offer automatic shipment of prescription refills to comply with the following requirements—

(i) *Voluntary participation.* Provide automatic shipments only to Part D enrollees that opt-in, on a drug-by-drug basis, after an initial fill.

(ii) *Enrollee notification.* (A) Send a minimum of two (2) shipping reminders to the Part D enrollee prior to shipment of each prescription refill.

(B) Network pharmacies must provide the shipping reminders by hard copy mailing, telephone, electronic delivery, or other comparable means of communication.

(C) All types of reminders must, at a minimum, include the name of the Part D drug, any applicable cost sharing, the scheduled shipping date, instructions on how to cancel the pending automatic shipment, and instructions on how to opt-out of any future automatic shipments.

(iii) *Refund policy.* Return any cost sharing paid by the Part D enrollee for any shipped prescription refills that such Part D enrollee reports as unneeded or otherwise unwanted, regardless of whether the drug is returned to the network pharmacy, and reverse the claim.

(iv) *Discontinuation.* (A) Stop automatic shipments if the enrollee, the enrollee's provider, or the enrollee's authorized representative requests to opt-out of automatic shipments at any time.

(B) Stop automatic shipments upon receiving notification that the Part D

enrollee has entered a skilled nursing facility or elected hospice coverage.

* * * * *

(i) * * *

(6) If the Part D Plan sponsor delegates any of the following functions to a first tier, downstream, or related entity, the Part D sponsor's written arrangements must state that a termination initiated by such entity must provide, at minimum, 60-days' prior notice and have an effective termination date that coincides with the end of a calendar month:

(i) Authorization, adjudication, and processing of prescription drug claims at the point of sale;

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers;

(iii) Operation of an enrollee appeals and grievance process; or

(iv) Contracting with or selection of prescription drug providers for inclusion in the Part D sponsor's network.

* * * * *

■ 74. Section 423.507 is amended by revising paragraph (a)(3) to read as follows:

§ 423.507 Nonrenewal of contract.

* * * * *

(a) * * *

(3)(i) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years in the PDP region or regions served by the contract unless there are circumstances that warrant special consideration, as determined by CMS.

(ii) If a PDP sponsor does not renew any of its PBPs in a PDP region, CMS cannot approve plan bids submitted by the organization in that PDP region for 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(iii) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.

* * * * *

■ 75. Section 423.508 is amended by revising paragraph (e) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

* * * * *

(e) *Agreement to limit new Part D applications.* (1) As a condition of the consent to a mutual termination, CMS will require, as a provision of the termination agreement language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions in the PDP region or regions served by the contract for a period up to 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(2) A PDP sponsor that agrees to terminate its offering of PBPs in a PDP region also agrees that it will not be eligible to apply to resume offering plans in that region for 2 years.

(3) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.

* * * * *

■ 76. Section 423.521 is added to subpart K to read as follows:

§ 423.521 Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the Part D sponsor a notice of final settlement. The notice of final settlement contains at least the following information:

(1) A final settlement amount, which may be either an amount due to the Part D sponsor, or an amount due from the Part D sponsor, or $0 if nothing is due to or from the Part D sponsor, for the contract that has been consolidated, nonrenewed, or terminated;

(2) Relevant banking and financial mailing instructions for Part D sponsors that owe CMS a final settlement amount;

(3) Relevant CMS contact information, and;

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 423.522.

(b) *Request for an appeal.* A Part D sponsor that disagrees with the final settlement amount will have 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 423.522.

(1) If a Part D sponsor agrees with the final settlement amount, no response is required.

(2) If a Part D sponsor disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS will not consider subsequent requests for appeal.

(c) *Actions if a Part D sponsor does not request an appeal.* (1) For Part D sponsors that are owed money by CMS, CMS will remit payment to the Part D sponsor within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For Part D sponsors that owe CMS money, the Part D sponsor will be required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the Part D sponsor fails to remit payment within that 120-calendar-day period, CMS will refer the debt owed to CMS to the Department of Treasury for collection.

(d) *Actions following a request for appeal.* If a Part D sponsor responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS will conduct a review process under the process described at § 423.522.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under paragraph (a) of this section, is issued to the Part D sponsor, CMS will no longer apply retroactive payment adjustments to the terminated, consolidated or nonrenewed contract and there will be no adjustments applied to amounts used in the calculation of the final settlement amount.

■ 77. Section 423.522 is added to subpart K to read as follows:

§ 423.522 Requesting an appeal of the final settlement amount.

(a) *Appeals process.* If a Part D sponsor does not agree with the final settlement amount described in § 423.521(a) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the final settlement amount described in § 423.521(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 days from the date that CMS issued the notice of final settlement to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must:

(A) Specify the calculations with which the Part D sponsor disagrees and the reasons for its disagreement;

(B) Include evidence supporting the assertion that CMS' calculation of the final settlement amount is incorrect; and

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS' reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date;

(B) CMS provides a copy of the record that was before CMS when CMS made its decision to the hearing officer;

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review will be conducted in the following manner:

(i) *Manner and timing of request.* A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review;

(ii) *Discretionary review.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding;

(iii) *Administrator's review.* If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision;

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS' calculation of the final settlement amount. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The Part D sponsor bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

(c) *Stay of financial transaction until appeals are exhausted.* If a Part D sponsor requests review of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount will be stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the Part D sponsor fails to request further review within the applicable 15-calendar-day timeframe, CMS will communicate with the Part D sponsor to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

(d) *Continued compliance with other law required.* Nothing in this section limits a Part D sponsor's responsibility to comply with any other statute or regulation, including under section 1128J(d) of the Social Security Act.

■ 78. Section 423.530 is added to subpart K to read as follows:

§ 423.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of plan crosswalk.* A plan crosswalk is the movement of enrollees from one plan benefit package (PBP) in a PDP contract to another PBP under a PDP contract between a Part D Sponsor and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* (i) Plan crosswalks between PBPs under one PDP contract and PBPs under another PDP contract are prohibited unless both the PDP sponsors with which CMS contracts are the same legal entity or have the same parent organization.

(ii) Plan crosswalks are prohibited that split the enrollment of one PBP into multiple PBPs.

(iii) Plan crosswalks are prohibited from a PBP offering basic prescription drug coverage to a PBP offering enhanced alternative coverage.

(3) *Compliance with renewal/non-renewal rules.* The PDP sponsor must comply with renewal and non-renewal rules in §§ 423.506 and 423.507 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under § 423.30 in order to be moved from one PBP to another PBP.

(5) *Applicability to employer group health or waiver plans.* Nothing in this section permits the crosswalk of enrollees in an employer group health or waiver plan PBP to another PBP outside the usual process for enrollment in employer group health or waiver plans.

(b) *Mandatory plan crosswalks.* A Part D sponsor of a PDP must perform a plan crosswalk in the following circumstances:

(1) *Renewal of a PBP offering basic prescription drug coverage.* A PDP sponsor that plans to continue operating a PBP offering basic prescription coverage in the same service area for the upcoming contract year must crosswalk enrollment from the PBP offering basic prescription drug coverage in the current contract year into a PBP offering basic prescription drug coverage under the same PDP contract in the upcoming contract year. The PBP for the upcoming contract year must retain the same plan ID as the PBP for the current contract year;

(2) *Renewal of a PBP offering enhanced alternative drug coverage.* A PDP sponsor that plans to continue operating a PBP offering enhanced alternative coverage in the same service area for the upcoming contract year must crosswalk enrollment from the PBP offering enhanced alternative drug coverage in the current contract year into a PBP offering enhanced alternative drug coverage in the upcoming contract year. The PBP for the upcoming contract

year PBP must retain the same plan ID as the PBP for the current contract year.

(c) *Plan crosswalk exceptions.* A Part D sponsor of a PDP may perform a plan crosswalk in the following circumstances after receiving approval from CMS under the procedures described in paragraph (d) of this section.

(1) *Consolidated renewals.* If a PDP sponsor wishes to non-renew a PBP offering enhanced alternative prescription drug coverage under a PDP contract that is not non-renewing or reducing its service area so that the contract no longer includes the service area of the non-renewing PBP, it may crosswalk enrollment from the non-renewing PBP into a PBP offered under the contract in the upcoming contract year.

(i) The plan ID for the upcoming contract year PBP must be the same plan ID as one of PBPs for the current contract year.

(ii) The PBPs being consolidated must be under the same PDP contract.

(iii) A PBP offering basic prescription drug coverage may not be discontinued if the PDP contract continues to offer coverage (other than employer group waiver plans) in the service area of the PBP.

(iv) Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering either enhanced alternative or basic prescription drug coverage.

(v) If the PDP contract includes more than one renewing PBP into which enrollment of the non-renewing PBP can be crosswalked, the enrollment of the non-renewing PBP must be crosswalked into the renewing PBP that will result in lowest increase in monthly premiums for the enrollees.

(vi) A plan crosswalk will not be approved under this paragraph if it will result in a premium increase for the following benefit year (as reflected in the bid for the receiving PBP submitted on the first Monday in June) that is higher than the greater of:

(A) The current year's premium for the non-renewing PBP; or

(B) The current year's average base beneficiary premium, as described in § 423.286(c) of this part, for the PDP region in which the PBP operates.

(vii) If an organization that non-renews an enhanced alternative PBP does not request and receive a plan crosswalk exception as provided in paragraph (d) of this section, CMS will not approve a new enhanced alternative PBP in the same service area as the non-renewing PBP in the following contract year.

(2) *Contract consolidations.* If a PDP sponsor non-renews all or part of the service area of its contract with CMS pursuant to §§ 423.507 or 423.508, the enrollees of the non-renewing PBPs may be crosswalked into one or more PBPs in another PDP contract (the surviving contract).

(i) The non-renewing PDP contract and the surviving contract must be held by the same legal entity or by legal entities with the same parent organization.

(ii) The approved service area of the surviving contract must include the service area of the non-renewing PBPs whose enrollment will be crosswalked into the surviving contract.

(iii) Enrollment may be crosswalked between PBPs offering the same type of prescription drug coverage (basic or enhanced alternative).

(iv) Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering basic prescription drug coverage.

(v) Enrollment from a PBP offering enhanced alternative coverage must be crosswalked into the PBP in the surviving contract that will result in the lowest premium increase.

(vi) A plan crosswalk will not be approved under this paragraph if it will result in a premium increase for the following benefit year (as reflected in the bid for the receiving PBP submitted on the first Monday in June) that is higher than the greater of:

(A) The current year's premium for the non-renewing PBP; or

(B) The current year's average base beneficiary premium, as described in § 423.286(c) of this part, for the region in which the PBP operates.

(d) *Procedures.* (1) A PDP sponsor must submit all plan crosswalks described in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline.

(2) A PDP sponsor must submit all plan crosswalk exception requests described in paragraph (c) of this section in writing through the plan crosswalk exceptions process in HPMS by the plan crosswalk exception request deadline announced annually by CMS. CMS verifies the requests and notifies requesting PDP sponsors of the approval or denial after the crosswalk exception request deadline.

■ 79. Section 423.551 is amended by revising paragraph (e) to read as follows

§ 423.551 General provisions.

* * * * *

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The current PDP sponsor, with respect to the affected contract, has substantially failed to comply with the regulatory requirements pursuant to § 423.510(a)(4)(ix) and the contract may be subject to intermediate enrollment and marketing sanctions as outlined in § 423.750(a)(1) and (3); intermediate sanctions imposed as part of this section will remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i) If the new owner does not participate in the Medicare program in the same service area as the affected contract, it must apply for, and enter into, a contract in accordance with subpart K of this part and part 422 if applicable; and, if the application is conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under § 423.551(d) for review and approval by CMS; or

(ii) If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions as outlined in this (e)(1), submit the documentation required under paragraph (d) of this section for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (d)(1)(i) or (ii) of this section within 30 days of imposition of intermediate sanctions as outlined in (d)(1) of this section, the existing contract will be subject to termination in accordance with § 423.509(a)(4)(ix).

* * * * *

■ 80. Section 423.562 is amended by revising paragraph (a)(1)(v) to read as follows:

§ 423.562 General provisions.

(a) * * *

(1) * * *

(v) Appeal procedures that meet the requirements of this subpart for issues that involve at-risk determinations. Determinations made in accordance with the processes at § 423.153(f) are collectively referred to as an at-risk determination, defined at § 423.560, made under a drug management program.

* * * * *

■ 81. Section 423.760 is amended by removing paragraph (b)(3)(i)(E) and revising paragraph (b)(3)(ii).

The revision reads as follows:

§ 423.760 Definitions for calculating penalty amounts.

* * * * *

(b) * * *

(3) * * *

(ii) *Calculation of penalty amounts.* (A) CMS will set minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(B) CMS will announce the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(C) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

* * * * *

■ 82. Section 423.773 is amended by:

■ a. Revising paragraph (b)(1);

■ b. Removing the phrase ''For subsequent years,'' and adding in its place the phrase ''For years 2007 through 2023,'' in paragraph (b)(2)(ii);

■ c. Adding paragraph (b)(2)(iii); and

■ d. Revising paragraph (d) introductory text.

The revisions and addition read as follows:

§ 423.773 Requirements for eligibility.

* * * * *

(b) * * *

(1) Has income below 135 percent of the FPL applicable to the individual's family size or, with respect to a plan year beginning on or after January 1, 2024, has income below 150 percent of the FPL applicable to the individual's family size; and

(2) * * *

(iii) For years beginning on or after January 1, 2024, the amount of resources specified at paragraph (d)(2) of this section.

* * * * *

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who, for plan years beginning before January 1, 2024—

* * * * *

■ 83. Section 423.780 is amended by revising paragraph (d) introductory text to read as follows:

§ 423.780 Premium subsidy.

* * * * *

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy for plan years beginning before January 1, 2024, based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

* * * * *

■ 84. Section 423.2261 is amended by revising paragraph (a)(2) and removing paragraph (a)(3).

The revision reads as follows:

§ 423.2261 Submission, review, and distribution of materials.

* * * * *

(a) * * *

(2) Materials must be submitted to the HPMS Marketing Module by the Part D sponsor or, where materials have been developed by a Third Party Marketing Organization for multiple Part D sponsors or plans, by a Third Party Marketing Organization with prior approval of each Part D sponsor on whose behalf the materials were created.

* * * * *

■ 85. Section 423.2262 is amended by revising paragraph (a)(1)(ii) and adding paragraph (a)(1)(xviii) to read as follows:

§ 423.2262 General communications materials and activity requirements.

* * * * *

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that has been published in either the current contract year or prior contract year.

* * * * *

(xviii) Use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card in a misleading way.

* * * * *

■ 86. Section 423.2263 is amended by adding paragraphs (b)(8) through (10) to read as follows:

§ 423.2263 General marketing requirements.

* * * * *

(b) * * *

(8) Advertise benefits that are not available to beneficiaries in the service area where the marketing appears, unless unavoidable in a local market.

(9) Market any products or plans, benefits, or costs, unless the Part D sponsor or marketing name(s) as listed in HPMS of the entities offering the referenced products or plans, benefits, or costs are identified in the marketing material.

(i) Part D sponsor or marketing names must be in 12-point font in print and may not be in the form of a disclaimer or in fine print.

(ii) For television, online, or social media the Part D sponsor or marketing name(s) must be either read at the same pace as the phone number or must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number or benefits.

(iii) For radio or other voice-based advertisements, Part D sponsor or marketing names must be read at the same pace as phone numbers.

(10) Part D sponsors may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

* * * * *

■ 87. Section 423.2264 is amended by:

■ a. Adding paragraph (a)(2)(i)(A) and reserved paragraph (a)(2)(i)(B);

■ b. Revising paragraphs (b)(2);

■ c. Removing paragraphs (c)(1)(ii)(C) and (E);

■ d. Redesignating paragraph (c)(1)(ii)(D) and new paragraph (c)(1)(ii)(C); and

■ e. Revising paragraphs (c)(2)(i), (c)(3)(i), and (c)(3)(iii)(A) and (B).

The addition additions and revisions read as follows:

§ 423.2264 Beneficiary contact.

* * * * *

(a) * * *

(2) * * *

(i) * * *

(A) Contact is considered to be unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable time and date, was previously scheduled.

(B) [Reserved]

* * * * *

(b) * * *

(2) If the Part D sponsor reaches out to beneficiaries regarding plan business, as outlined in this section, the Part D sponsor must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

(c) * * *

(2) * * *

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.

* * * * *

(3) * * *

(i) At least 48 hours prior to the personal marketing appointment

beginning, the Part D plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

* * * * *

(iii) * * *

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 6 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(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; such Scope of Appointment is valid for six (6) months following the beneficiary's signature date.

* * * * *

■ 88. Section 423.2265 is amended by removing and reserving paragraph (b)(12) and revising paragraph (c)(1)(vi).

The revision reads as follows:

§ 423.2265 Websites.

* * * * *

(c) * * *

(1) * * *

(vi) Utilization Management Criteria for physicians and enrollees.

* * * * *

■ 89. Section 423.2267 is amended by—

■ a. Redesignating paragraph (a)(3) as paragraph (a)(5);

■ b. Adding new paragraph (a)(3) and pargraph (a)(4);

■ c. Revising paragraph (e)(4) introductory text;

■ d. Adding paragraph (e)(4)(viii);

■ e. Revising paragraphs (e)(13) introductory text, (e)(32)(vi), and (e)(41); and

■ f. Adding paragraphs (e)(42) through (44).

The revisions and additions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(a) * * *

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section and/or accessible format using auxiliary aids and services upon receiving a request for the materials in another language or accessible format using auxiliary aids and services or when otherwise learning of the enrollee's preferred language and/or need for an accessible format using auxiliary aids and services. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) of this chapter for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan as defined at § 422.2 of this chapter, or applicable integrated plan as defined at § 422.561 of this chapter, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard in paragraph (a)(2) of this section.

* * * * *

(e) * * *

(4) *Pre-enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

* * * * *

(viii) Effect on current coverage.

* * * * *

(13) *Non-renewal notice.* This is a standardized communications material through which plans must provide the information required under § 423.507.

* * * * *

(32) * * *

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section; and

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all Part D sponsors in the service area the disclaimer consists of the statement: ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area which are plans offered by [insert list of Part D sponsors here]. Please contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program to get information on all of your options.'' If the TPMO sells for all Part D sponsors in the service area the disclaimer consists of the statement: ''We offer the following plans in your area [insert list of Part D sponsors]. You can always contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program for help with plan choices.'' The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

(42) *Required Content when offering defined standard coverage.* This is model content which—

(i) Applies to all plans offering defined standard coverage (as defined at § 423.100);

(ii) Must be used in all relevant communications (as defined at § 423.2260) that pertain to the formulary (as defined at § 423.4) or preferential status of covered Part D drugs; and

(iii) When discussing the Part D sponsor's formulary, conveys that all covered drugs have a single-tier benefit structure.

(43) *Comprehensive medication review—written summary.* This is the standardized communications material Part D sponsors must provide to all MTM program enrollees who receive a comprehensive medication review, as required under § 423.153(d)(1)(vii)(B).

(44) *Safe disposal information.* This is model communications material Part D sponsors must provide to all enrollees targeted for its MTM program, as required under § 423.153(d)(1)(vii)(E).

■ 90. Section 423.2272 is amended by adding paragraph (e) to read as follows:

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

■ 91. Section 423.2274 is amended by adding paragraph (c)(12), revising paragraph (g)(2)(ii), and adding paragraph (g)(4) to read as follows:

§ 423.2274 Required materials and content.

* * * * *

(c) * * *

(12) Ensure that, prior to an enrollment CMS' required questions and

topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), premiums, and other services (such as over-the-counter medications and other incentives).

* * * * *

(g) * * *

(2) * * *

(ii) Record all marketing, sales, and enrollment calls, including calls occurring via web-based technology, in their entirety.

* * * * *

(4) Personal beneficiary data collected by a TPMO may not be distributed to other TPMOs.

■ 92. Subpart Y is added to read as follows:

Subpart Y—Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

Sec.

Subpart Y—Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

§ 423.2500 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–14 of the Social Security Act.

(b) *Scope.* This subpart sets forth the requirements for the Limited Income Newly Eligible Transition (LI NET) program that begins no later than January 1, 2024. Under this program, eligible individuals are provided transitional coverage for part D drugs.

§ 423.2504 LI NET eligibility and enrollment.

(a) *Eligibility.* An individual is eligible for LI NET coverage if they satisfy the criteria at paragraph (a)(1) or (2) of this section.

(1) *LIS-eligible.* The individual is a low-income subsidy eligible individual as defined at § 423.773 and—

(i) Has not yet enrolled in a prescription drug plan or an MA–PD plan; or

(ii) Has enrolled in a prescription drug plan or MA–PD plan but their coverage has not yet taken effect.

(2) *Immediate need individuals.* An individual who states their eligibility for LIS and immediate need for their prescription, but whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale, will be granted immediate need LI NET coverage.

(i) Immediate need individuals may provide documentation to the LI NET sponsor to establish LIS eligibility. Documentation may include, but is not limited to:

(A) A copy of the beneficiary's Medicaid card that includes their name and the eligibility date;

(B) A copy of a letter from the State or SSA showing LIS status;

(C) The date that a verification call was made to the State Medicaid Agency, the name and telephone number of the State staff person who verified the Medicaid period, and the Medicaid eligibility dates confirmed on the call;

(D) A copy of a State document that confirms active Medicaid status;

(E) A screen-print from the State's Medicaid systems showing Medicaid status; or

(F) Evidence at point-of-sale of recent Medicaid billing and payment in the pharmacy's patient profile.

(ii) If CMS cannot confirm the individual's eligibility during the period of LI NET coverage, the individual will not be auto-enrolled into a standalone Part D plan in accordance with § 423.34(d) following their LI NET coverage.

(b) *Enrollment.* Individuals are enrolled into the LI NET program as follows:

(1) *Automatic enrollment.* Beneficiaries who are LIS-eligible and whose auto-enrollment into a Part D plan (as outlined in § 423.34(d)(1)) has not taken effect will be automatically enrolled by CMS into the LI NET program unless the beneficiary has affirmatively declined enrollment in Part D per § 423.34(e);

(2) *Point-of-sale enrollment.* An individual with an immediate need whose claim is submitted at the point-of-sale and billed to LI NET will be enrolled into the LI NET program by the LI NET sponsor; or

(3) *Direct reimbursement request.* An individual who is LIS-eligible and who submits receipts for reimbursement for claims paid out of pocket will be retroactively enrolled into the LI NET program by the LI NET sponsor. The LI NET sponsor has 14 calendar days to reply with a coverage decision; or

(4) *LI NET application form.* An individual who is not enrolled through the methods in paragraphs (b)(1) though (3) of this section may submit an application form to the LI NET sponsor with supporting documentation demonstrating their LIS status. The LI NET sponsor will periodically check for eligibility and enroll applicants once eligibility is confirmed.

(c) *Duration of LI NET enrollment.* (1) Enrollment begins on the first day of the month an individual is identified as eligible under this section and ends after 2 months, with a longer LI NET enrollment for those with retroactive coverage per paragraph (c)(2) of this section.

(2) Retroactive LI NET coverage begins on the date an individual is identified as eligible for a low-income subsidy as a full-benefit dual eligible or an SSI benefit recipient, or 36 months prior to the date such individual enrolls in (or opts out of) Part D coverage, whichever is later. LI NET coverage ends with enrollment into a Part D plan or opting out of Part D coverage.

(d) *Ending LI NET enrollment.* An individual's enrollment in the LI NET program ends when:

(1) The individual is auto-enrolled into a standalone Part D plan in accordance with the guidelines at § 423.34(d) and that coverage has taken effect.

(2) The individual elects another Part D plan and that coverage has taken effect.

(3) The individual voluntarily disenrolls from the LI NET program.

(4) The individual is involuntarily disenrolled under § 423.44(b).

(5) LIS-eligibility for an individual in LI NET due to an immediate need cannot be confirmed within the period of LI NET coverage.

§ 423.2508 LI NET benefits and beneficiary protections.

(a) *Formulary.* The LI NET program provides access to all Part D drugs under an open formulary.

(b) *Network.* The LI NET sponsor must allow their network and out-of-network pharmacies that are in good standing, as determined by CMS, to process claims under the program. Licensed pharmacies that have not been revoked from Medicare under § 424.535, that do not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs pursuant to section 1128

of the Act and from Medicare under section 1156 of the Act (unless waived by the OIG), and do not appear on the preclusion list as defined at § 423.100 are considered to be in good standing for the LI NET program.

(c) *Safety.* The following provisions necessary to improve patient safety and ensure appropriate dispensing of medication apply to the LI NET program and LI NET sponsor, as applicable:

(1) Section 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) *Cost sharing.* (1) LI NET beneficiaries under § 423.2504(a)(1) will pay the applicable cost sharing for their low-income category as established for each year in the Rate Announcement publication specified in § 422.312 of this chapter.

(2) LI NET beneficiaries under § 423.2504(a)(2) will pay the cost sharing associated with the category of non-institutionalized full-benefit dual eligible individuals with incomes above 100% of the Federal poverty level and full-subsidy-non-FBDE individuals. If the beneficiary is later confirmed to belong to a different LIS category, the LI NET sponsor must reimburse the beneficiary for the difference between the cost sharing they paid versus what they would have paid in their LIS category.

(e) *Appeals.* LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of this part.

§ 423.2512 LI NET sponsor requirements.

The LI NET program is administered by one or more Part D sponsor(s) that meet all of the requirements in paragraphs (a) through (c) of this section.

(a) *Pharmacies and access to Part D drugs.* (1) The LI NET sponsor must be a PDP sponsor that has an established contracted pharmacy network in all geographic areas of the United States in which low-income subsidies are available.

(2) The LI NET sponsor must meet the requirements for providing access to Part D drugs under § 423.120(a), (c), and (d).

(b) *Experience.* The LI NET sponsor must have a minimum of two consecutive years contracting with CMS as a Part D sponsor.

(c) *Other LI NET sponsor requirements.* The LI NET sponsor must:

(1) Have the technical capability and the infrastructure to provide immediate, current, and retroactive coverage for LI NET enrollees;

(2) Have the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible LI NET enrollees.

(3) Identify, develop, and carry out outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program.

(4) Establish and manage a toll-free customer service telephone line and fax line that can be accessed by pharmacy providers and beneficiaries, or others acting on their behalf, for purposes that include but are not limited to: handling inquiries about services under the LI NET program, providing the status of eligibility or claims, and having the ability to accept best available evidence.

(5) Timely respond to beneficiary requests for reimbursement of claims by issuing reimbursement for eligible claims submitted by beneficiaries no later than 30 days after receipt, or, if the drug is not covered, the LI NET sponsor has 14 days to send communication to the beneficiary with a reason for the denial.

(6) Adjudicate claims from out-of-network pharmacies according to the LI NET sponsor's standard reimbursement for their network pharmacies.

§ 423.2516 Selection of LI NET sponsor and contracting provisions.

(a) *Appointment by CMS.* CMS appoints a Part D sponsor that meets the requirements at § 423.2512 to serve as the LI NET sponsor.

(b) *Selection criteria.* In appointing a LI NET sponsor, CMS evaluates the following:

(1) Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in § 423.34;

(2) Pharmacy access as outlined in § 423.120;

(3) Past performance, including Star Ratings (as detailed in § 423.186), previous intermediate sanctions (as detailed in § 423.750), and consistent with past performance in § 423.503(b); and

(4) Ability to meet the requirements listed in § 423.505 that are not waived under § 423.2536.

(c) *Term of appointment.* The term of the appointment will be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per § 423.2524(b)) to determine payment rates for the upcoming year.

§ 423.2518 Intermediate sanctions for the LI NET sponsor.

In the event it is determined that the LI NET sponsor violated its contract, CMS may impose intermediate sanctions as outlined in subpart O of this part.

§ 423.2520 Non-renewal or termination of appointment.

(a) *Notice of non-renewal.* If the LI NET sponsor decides for any reason to non-renew its existing contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS notifies the LI NET sponsor by January 1 of the year before the next contract year.

(b) *Selection of successor and transition period.* After a notice of non-renewal or termination, CMS selects a successor for the LI NET contract from among potentially eligible entities (as detailed in § 423.2516). The outgoing LI NET sponsor must coordinate with the successor for a period of no less than 3 months to ensure seamless transition of the LI NET program, including timely transfer of any data or files.

(c) *Immediate termination for cause.* (1) Notwithstanding paragraph (a) of this section, CMS may immediately terminate the existing LI NET contract for any of the reasons specified at § 423.509(a)(4)(i) and (xii) or (b)(2)(i)(A) and (B).

(2) CMS sends notice of an immediate termination as specified at § 423.509(b)(2)(ii).

(d) *Appeal rights.* Subpart N of this part applies to a termination under paragraph (c) of this section.

§ 423.2524 Bidding and payments to LI NET sponsor.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) Submission of bids and related information.

(1) The submission of LI NET bids and related information must follow the requirements and limitations in § 423.265(b), (c), (d)(1), (d)(2)(i), (ii), (iv), and (v), (d)(4) and (6), and (e).

(2) The review, negotiation, and approval of the LI NET bid would follow the provisions in § 423.272(a) and (b)(1) and (4).

(3) Basic rule for bid. The bid must reflect the LI NET sponsor's estimate of its revenue needs for Payment Rates A and B per paragraph (c) of this section.

(c) *Monthly payments.* CMS provides advance monthly LI NET payments equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid, as outlined in paragraph (b) of this section. LI NET payments are made on a prospective per-member, per-month basis.

(1) Payment Rate A is an annual rate of payment for projected administrative costs. An annual percentage-based cap on Payment Rate A limiting the year over year increase to Payment Rate A is set as part of the bid review and negotiation under § 423.272(a).

(i) For the 2024 plan year, the LI NET sponsor includes in their bid the assumption that Payment Rate A cannot exceed a 2% increase from the prior year's Payment A, which is a figure CMS will provide to the LI NET sponsor.

(ii) For the 2025 plan going forward, the LI NET sponsor will specify their assumption for any increase needed to the prior year's Payment Rate A, submitting justification to CMS in their bid if the cap exceeds 2%.

(2) Payment Rate B reflects the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit.

(d) *Payment reconciliation and risk corridors*—(1) *Reconciliation.* CMS conducts LI NET payment reconciliation each year for Payment Rates A and B after the annual PDE data submission deadline has passed and makes the resulting payment adjustment consistent with § 423.343(a).

(2) *Risk corridors.* As part of LI NET payment reconciliation, CMS will apply risk corridors to Payment Rate B as follows:

(i) There will be no risk sharing in the symmetrical 1% risk corridor around the target amount as defined in § 423.308.

(ii) There will be symmetrical risk sharing of 0.1% beyond the 1% risk corridor.

(iii) To carry out this section, § 423.336(c) applies to LI NET.

(e) *Reopening.* The LI NET contract will be subject to payment reopenings per § 423.346 as applicable.

(f) *Payment appeals.* The LI NET sponsor can appeal under § 423.350.

(g) *Overpayments.* The overpayment provisions at §§ 423.352 and 423.360 apply to LI NET.

§ 423.2536 Waiver of Part D program requirements.

CMS waives the following Part D program requirements for the LI NET program:

(a) *General information.* Paragraphs (1) and (3)(B) of section 1860D–4(a) of the Act (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(b) *Formularies.* Subparagraphs (A) and (B) of section 1860D–4(b)(3) of the Act (relating to requirements on development and application of formularies; formulary development) and formulary requirements in §§ 423.120(b) and 423.128(e)(5) and (6).

(c) *Cost control and quality improvement requirements.* Provisions under subpart D of this part, including requirements about medication therapy management, are waived except for the provisions in § 423.2508(d)(1) through (5).

(1) Section 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) *Out-of-network access.* Section 423.124 Special rules for out-of-network access to Part D drugs at out-of-network pharmacies, except for § 423.124(a)(2), which applies to LI NET.

(e) *Medicare contract determinations and appeals.* Subpart N, except for the provisions that apply to LI NET in § 423.2520(d).

(f) *Risk-sharing arrangements.* Section 423.336(a), (b), and (d).

(g) *Certification of accuracy of data for price comparison.* Section 423.505(k)(6).

(h) *Part D communication requirements.* Portions of subpart V of this part related to Part D communication requirements that are inapplicable to LI NET, including:

(1) Section 423.2265(b)(4), (5), (11), and (13);

(2) Section 423.2265(c);

(3) Section 423.2266(a);

(4) Section 423.2267(e)(3) through (5), (9) through (12), (14) through (17), (25), (29), and (33); and

(5) Section 423.2274.

(i) *Medicare Coverage Gap Discount Program.* Subpart W of this part.

(j) *Requirements for a minimum medical loss ratio.* Subpart X of this part.

(k) *Recovery audit contractor Part C appeals process.* Subpart Z of this part.

Subpart Z—Recovery Audit Contractor Part D Appeals Process

■ 93. The heading for subpart Z is revised to read as set forth above.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 94. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 95. Section 460.6 is amended by revising the definition of ''contract year'' to read as follows:

§ 460.6 Definitions.

* * * * *

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 19 to 30 months, as determined by CMS, but in any event will end on December 31.

* * * * *

■ 96. Section 460.12 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 460.12 Application requirements.

(a) *Submission of application.* (1) An individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its service area and/or add a PACE center site must submit to CMS a complete application in the form and manner, including timeframes for submission, specified by CMS, that describes how the entity or PACE organization meets all requirements in this part.

(2) An individual authorized to act for an entity that seeks to become a PACE organization must submit an application to qualify as a Part D sponsor in the form and manner required by CMS pursuant to 42 CFR part 423, subpart K.

(b) * * *

(3) Any PACE application that does not include a signed and dated State assurances document that includes accurate service area information and the physical address of the PACE center, as applicable, is considered incomplete and invalid and will not be evaluated by CMS.

* * * * *

■ 97. Section 460.18 is amended by adding paragraphs (c) and (d) to read as follows:

§ 460.18 CMS evaluation of applications.

* * * * *

(c)(1) If, during the 12 months preceding the deadline established by CMS for the submission of an application or submission of a response to a CMS request for additional information, a PACE organization fails to comply with the requirements of the PACE program under any current or prior PACE program agreement or fails to complete a corrective action plan during the applicable 12-month period, CMS may deny an application based on the applicant's failure to comply with the requirements of the PACE program under any current or prior PACE program agreement even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with the requirements of the PACE program under a PACE program agreement for purposes of an application denial under paragraph (c)(1) of this section if any of the conditions in paragraphs (c)(1)(i)(A) through (D) of this section apply with respect to the applicant during the applicable 12-month review period. The applicant:

(A) Was subject to the imposition of an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40.

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 460.80(a) after the end of the trial period.

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Met or exceeded 13 points for compliance actions for any one PACE program agreement.

(*1*) CMS determines the number of points accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued under § 460.19(c)(3) during the performance period counts for 6 points.

(*ii*) Each warning letter issued under § 460.19(c)(2) during the performance period counts for 3 points.

(*iii*) Each notice of noncompliance issued under § 460.19(c)(1) during the performance period counts for 1 point.

(*2*) CMS adds all the point values for each PACE organization's program agreement to determine if the 13-point threshold described in paragraph (c)(1)(i)(D) of this section has been reached.

(ii) CMS may deny an application submitted by an organization that does not hold a PACE program agreement at the time of the submission if the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (c)(1)(i) of this section. This paragraph does not apply to a parent organization that completed the acquisition of a subsidiary that meets the criteria for denial within the 24 months preceding the application submission deadline.

(2) [Reserved]

(d) If CMS has terminated a PACE program agreement under § 460.50, or did not renew a PACE program agreement, and that termination or non-renewal took effect within the 38 months preceding the submission of an initial or expansion PACE application from the same organization, CMS may deny the application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant currently meets all of the requirements of this part.

* * * * *

■ 98. Section 460.19 is added to read as follows:

§ 460.19 Issuance of compliance actions for failure to comply with the terms of the PACE program agreement.

(a) CMS may take compliance actions as described in paragraph (c)(1) of this section if CMS determines that the PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and a State administering agency.

(1) CMS may determine that a PACE organization is out of compliance with requirements when the organization fails to meet performance standards articulated in sections 1894 and 1934 of the Social Security Act and regulations in this chapter.

(2) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an PACE organization is out of compliance when its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

(b) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(1) The nature of the conduct.

(2) The degree of culpability of the PACE organization.

(3) The actual or potential adverse effect on beneficiaries which resulted or could have resulted from the conduct of the PACE organization.

(4) The history of prior offenses by the PACE organization or its related entities.

(5) Whether the noncompliance was self-reported.

(6) Other factors which relate to the impact of the underlying noncompliance or to the PACE organization's inadequate oversight of the operations that contributed to the noncompliance.

(c) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(1) *Notice of noncompliance.* A notice of noncompliance may be issued for any failure to comply with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section.

(2) *Warning letter.* A warning letter may be issued for serious and/or continued noncompliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(3) *Corrective action plan.* (i) Corrective action plans are issued for particularly serious or continued noncompliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(ii) CMS issues a corrective action plan if CMS determines that the PACE organization has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, or must implement a detailed plan to correct the underlying causes of the noncompliance.

■ 99. Section 460.20 is amended by redesignating paragraphs (c) through (e) as paragraphs (d) through (f) and adding new paragraph (c).

The addition reads as follows:

§ 460.20 Notice of CMS determination.

* * * * *

(c) *Incomplete application due to the lack of required State assurances documentation.* An application that, upon submission, is determined to be incomplete under § 460.12(b)(3) will be withdrawn by CMS and the applicant will be notified accordingly. The applicant is not entitled to a fair hearing when CMS withdraws an incomplete application on this basis.

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■ 100. Section 460.40 is amended by revising paragraph (b) to read as follow:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(b) If CMS or the State administering agency makes a determination under § 460.50 that could lead to termination of a PACE program agreement, CMS may impose any of the sanctions specified at §§ 460.42 and 460.46. If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administrating agency has to determine that the circumstances in 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension.

■ 101. Section 460.64 is amended by revising paragraph (a)(5) and adding paragraph (a)(6) to read as follows:

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) * * *

(5) Be medically cleared for communicable diseases before engaging in direct participant contact and on an annual basis.

(i) Staff must be cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice, unless:

(A) The PACE organization conducts an individual risk assessment that meets the conditions specified in paragraph (a)(5)(iii) of this section, and

(B) The results of the risk assessment indicate the individual does not require a physical examination for medical clearance.

(ii) As part of the initial physical examination, staff must be determined to be free of active Tuberculosis disease.

(iii) If the PACE organization conducts a risk assessment on an individual under paragraphs (a)(5)(i)(A) and (B) of this section:

(A) Policies and procedures for conducting a risk assessment on each individual with direct participant contact must be based on accepted professional standards of care.

(B) The PACE organization's risk assessment must identify when a physical examination is required based on the results of the assessment.

(C) The results of the risk assessment must be reviewed by a registered nurse, physician, nurse practitioner, or physician assistant.

(D) At a minimum, the risk assessment must:

(*1*) Assess whether staff have been exposed to or have any symptoms of the following diseases: COVID–19, Diphtheria, Influenza, Measles, Meningitis, Meningococcal Disease, Mumps, Pertussis, Pneumococcal Disease, Rubella, Streptococcal Infection, Varicella Zoster Virus, and any other infectious diseases noted as a potential threat to public health by the CDC.

(*2*) Determine if staff are free of active Tuberculosis during the initial risk assessment.

(6) Have all immunizations up-to-date before engaging in direct participant contact, including, at a minimum, the vaccination requirements in § 460.74.

* * * * *

■ 102. Section 460.70 is amended by revising paragraph (a) to read as follows:

§ 460.70 Contracted services.

(a) *General rule.* The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, including, at a minimum, the medical specialties identified in paragraph (a)(1) of this section. The PACE organization does not need to have a written contract with entities that provide emergency services as described in § 460.100.

(1) At a minimum, except as noted in paragraph (a)(4) of this section, PACE organizations must have contracts in place for the following medical specialties:

(i) Anesthesiology.
(ii) Audiology.
(iii) Cardiology.
(iv) Dentistry.
(v) Dermatology.
(vi) Gastroenterology.
(vii) Gynecology.
(viii) Internal Medicine.
(ix) Nephrology.
(x) Oncology.
(xi) Ophthalmology.
(xii) Oral surgery.
(xiii) Orthopedic surgery.
(xiv) Otorhinolaryngology.
(xv) Plastic surgery.
(xvi) Pharmacy consulting services.
(xvii) Podiatry.
(xviii) Psychiatry.
(xix) Pulmonology.
(xx) Radiology.
(xxi) Rheumatology.
(xxii) General Surgery.
(xxiii) Thoracic and vascular surgery.
(xxiii) Urology.

(2) Contracts with medical specialists must be executed prior to enrollment of participants and must be maintained on an ongoing basis to ensure participants receive appropriate and timely access to all medically necessary care and services.

(3) A PACE organization is responsible for making all reasonable and timely attempts to contract with medical specialists. If at any time a PACE organization is unable to directly contract or maintain a contract with a specific specialty, the PACE organization must:

(i) Ensure care and services that would otherwise be provided to participants by a contracted specialist are provided and that the participant's needs are met through a different mechanism to include hospitalization, and

(ii) Promptly report the contracting issue to CMS and the SAA, including the attempts made to contract, the reason why the contract was not effectuated, and the PACE organization's plan to provide access to the necessary services.

(4) A PACE organization is not required to have a contract with a particular medical specialty if the PACE organization directly employs one or more individuals prior to contracting who are legally authorized, and if applicable, board certified in the participant medical specialty.

* * * * *

■ 103. Section 460.71 is amended by—
■ a. Revising paragraph (b)(4);
■ b. Redesignating paragraph (b)(5) and (6) as paragraphs (b)(6) and (7), respectively; and
■ c. Adding new paragraph (b)(5).

The revision and addition read as follow:

§ 460.71 Oversight of direct participant care.

* * * * *

(b) * * *

(4) Be medically cleared for communicable diseases before engaging in direct participant contact and on an annual basis as required under § 460.64(a)(5).

(5) Have all immunizations up-to-date before engaging in direct participant contact, including, at a minimum, the vaccine requirements identified in § 460.74.

* * * * *

■ 104. Section 460.98 is amended by:
■ a. Removing paragraph (b)(4);
■ b. Redesignating paragraph (b)(5) as paragraph (b)(4).
■ c. Redesignating paragraphs (c) through (e) as paragraphs (d) through (f), respectively;
■ d. Adding new paragraph (c);

The addition reads as follows:

§ 460.98 Service delivery.

* * * * *

(c) *Timeframes for arranging and providing services*—(1) *Medications.*

The PACE organization must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication.

(2) *All other services.* The PACE organization must arrange or schedule the delivery of interdisciplinary team approved services, other than medications, as identified in paragraph (c)(2)(i) of this section, as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the interdisciplinary team or member of the interdisciplinary team first approves the service, except as identified in paragraph (c)(3) of this section.

(i) Interdisciplinary team approved services include:

(A) Services approved by the full interdisciplinary team.

(B) Services approved by a member of the interdisciplinary team.

(C) Services ordered by a member of the interdisciplinary team.

(D) Care planned services.

(ii) [Reserved]

(3) *Routine or preventative services.* Routine or preventive services are excluded from the requirement in paragraph (c)(2) of this section when all of the following requirements are met:

(i) The PACE organization documents that they were unable to schedule the appointment due to circumstances beyond the control of the PACE organization.

(ii) The participant does not have a change in status that requires the service to be provided more quickly.

(iii) The PACE organization provides the service as expeditiously as the participant's condition requires.

(4) *Providing approved services.* Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs.

* * * * *

■ 105. Section 460.102 is amended by revising paragraph (d)(1) to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *

(1) The interdisciplinary team is responsible for the following for each participant:

(i) *Assessments and plan of care.* The initial assessment, periodic reassessments, and plan of care.

(ii) *Coordination of care.* Coordination and implementation of 24-hour care delivery that meets participant needs across all care settings, including but not limited to:

(A) Ordering, approving, or authorizing all necessary care.

(B) Communicating all necessary care and relevant instructions for care.

(C) Ensuring care is implemented as it was ordered, approved, or authorized by the IDT.

(D) Monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs.

(E) Promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant.

(iii) *Documenting recommended services.* 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).

(iv) *Consideration of recommended services.* The interdisciplinary team must review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists. Specifically, the interdisciplinary team must ensure the following requirements are met:

(A) The appropriate member(s) of the interdisciplinary team must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs within 24 hours from the time of the participant's discharge.

(B) The appropriate member(s) of the interdisciplinary team must review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 5 calendar days from the date the recommendation was made.

(C) If recommendations are authorized or approved by the interdisciplinary team or a member of the interdisciplinary team, the services must be promptly arranged and furnished under § 460.98(c).

* * * * *

■ 106. Section 460.104 is amended by revising paragraph (e) to read as follows:

§ 460.104 Participant assessments.

* * * * *

(e) *Changes to plan of care.* When the interdisciplinary team conducts semiannual or unscheduled reassessments, the interdisciplinary team must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments.

* * * * *

■ 107. Section 460.106 is revised to read as follows:

§ 460.106 Plan of care.

(a) *Basic requirement.* The interdisciplinary team members specified in § 460.102(b) must develop, evaluate, and if necessary revise a comprehensive person-centered plan of care for each participant. Each plan of care must take into consideration the most current assessment findings and must identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being.

(b) *Timeframes for developing, evaluating, and revising plan of care—* (1) *Initial plan of care.* The interdisciplinary team must complete the initial plan of care within 30 calendar days of the participant's date of enrollment.

(2) *Semi-annual plan of care evaluation.* At least once every 180 calendar days the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to each participant's plan of care.

(3) *Change in participant's status.* (i) Except as specified in paragraph (b)(3)(ii) of this section, the interdisciplinary team must complete a re-evaluation of, and if necessary, revisions to a participant's plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status, or more expeditiously if the participant's condition requires. For purposes of this section, a ''change in participant's status'' means a major decline or improvement in a participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status, and requires interdisciplinary team review or revision of the care plan, or both.

(ii) If a participant is hospitalized within 14 calendar days of the change in participant status, the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital.

(c) *Content of plan of care.* At a minimum, each plan of care must meet the following requirements:

(1) Identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring. At a minimum, the care plan must address the following factors:

(i) Vision;

(ii) Hearing;

(iii) Dentition;

(iv) Skin integrity;

(v) Mobility;

(vi) Physical functioning, including activities of daily living;

(vii) Pain management;

(viii) Nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs;

(ix) The participant's ability to live safely in the community, including the safety of their home environment;

(x) Home care;

(xi) Center attendance;

(xii) Transportation; and

(xiii) Communication, including any identified language barriers.

(2) Identify each intervention (the care and services) needed to meet each medical, physical, emotional, and social needs, except: the plan of care does not have to identify the medications needed to meet the participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record;

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.

(4) Identify how each intervention will be implemented, including a timeframe for implementation.

(5) Identify a measurable goal for each intervention.

(6) Identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified.

(7) The participant's preferences and goals of care.

(d) *Implementation of the plan of care.* (1) The team must continuously implement, coordinate, and monitor the plan of care regardless of whether the services are furnished by PACE employees or contractors, across all care settings.

(2) The team must continuously evaluate and monitor the participant's medical, physical, emotional, and social needs as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other employees or contractors.

(e) *Participant and caregiver involvement in plan of care.* (1) The interdisciplinary team must develop, evaluate and revise each plan of care in collaboration with the participant, the participant's caregiver, or both.

(2) The interdisciplinary team must review and discuss each plan of care with the participant and/or the participant's caregiver before the plan of care is completed to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The team must establish and implement a process to document and maintain records related to all requirements for plans of care, in the participant's medical record, and ensure that the most recent care plan is available to all employees and contractors within the organization as needed.

■ 108. Section 460.112 is amended by—

■ a. Removing paragraph (d);

■ b. Redesignating paragraphs (a) through (c) as paragraphs (b) through (d);

■ c. Adding new paragraph (a);

■ d. Adding paragraph (b)(8);

■ e. Revising newly redesignated paragraph (c) introductory text and paragraph (e)(1);

■ f. Adding paragraph (c)(5);

■ g. Revising paragraph (e)(1);

■ g. Redesignating paragraphs (e)(2) through (6) as (e)(3) through (7);

■ h. Adding new paragraph (e)(2);

■ i. Revising the paragraph (g) subject heading;

■ j. Revising paragraph (g)(2); and

■ k. Adding paragraph (g)(3).

The revisions and additions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Right to treatment.* Each participant has the right to appropriate and timely treatment for their health conditions, including the right to:

(1) Receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being; and

(2) Access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

(b) * * *

(8) To have all information regarding PACE services and treatment options explained in a culturally competent manner.

(c) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health decisions. A participant has the right to have all information in this section shared with their designated representative. Specifically, each participant has the following rights:

* * * * *

(5) To be fully informed of the following, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services:

(i) A description of the PACE organization's palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving.

(ii) Whether palliative care, comfort care, or end-of-life care services (as applicable) will be provided in addition to or in lieu of the care the participant is currently receiving.

(iii) Identify all services that will be impacted and provide a detailed explanation of how the services will be impacted if the participant and/or designated representative elects to initiate palliative care, comfort care, or end-of-life care, including but not limited to the following types of services.

(A) Physician services, including specialist services.

(B) Hospital services.

(C) Long-term care services.

(D) Nursing services.

(E) Social services.

(F) Dietary services.

(G) Transportation.

(H) Home care.

(I) Therapy, including physical, occupation, and speech therapy.

(J) Behavioral health.

(K) Diagnostic testing, including imaging and laboratory services.

(L) Medications.

(M) Preventative healthcare services.

(N) PACE center attendance.

(iv) The right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason, either verbally or in writing.

* * * * *

(e) * * *

(1) To make health care decisions, including the right to:

(i) Have all treatment options fully explained;

(ii) Refuse any and all care and services; and

(iii) Be informed of the consequences their decisions may have on their health and/or psychosocial status.

(2) To fully understand the PACE organization's palliative care, comfort

care, and end-of-life care services. Specifically, the PACE organization must do all of the following before palliative care, comfort care, or end-of-life care services can be initiated:

(i) Fully explain the applicable treatment options;

(ii) Provide the participant with written information about their treatment options, in accordance with paragraph (c)(5) of this section.

(iii) Obtain written consent from the participant or designated representative prior to initiating palliative care, comfort care, or end-of-life care.

* * * * *

(g) *Complaints, requests, and appeals.*

* * *

(2) To request services from the PACE organizations, its employees, or contractors through the process described in § 460.121.

(3) To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122.

■ 109. Section 460.120 is revised to read as follow:

§ 460.120 Grievance process.

(a) *Written procedures.* A PACE organization must have a formal written process to promptly identify, document, investigate, and resolve all medical and nonmedical grievances in accordance with the requirements in this part.

(b) *Definition of grievance.* For purposes of this part, a grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant.

(c) *Grievance process notification to participants.* Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process in understandable language, including:

(1) A participant or other individual specified in paragraph (d) of this section has the right to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal.

(2) A Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services.

(3) The requirements under paragraphs (b) and (d) through (k) of this section.

(d) *Who can submit a grievance.* Any of the following individuals can submit a grievance:

(1) The participant;

(2) The participant's family member;

(3) The participant's designated representative;or

(4) The participant's caregiver.

(e) *Methods for submitting a grievance.*(1) Any individual as permitted under paragraph (d) of this section may file a grievance with the PACE organization either orally or in writing.

(2) The PACE organization may not require a written grievance to be submitted on a specific form.

(3) A grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants.

(f) *Conducting an investigation.* The PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known.

(g) *Grievance resolution and notification timeframes.* (1) The PACE organization must take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance.

(2) The PACE organization must notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with paragraph (g)(1) of this section.

(h) *Expedited grievances.* The PACE organization must resolve and notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 24 hours after the time the PACE organization receives the oral or written grievance if the nature of the grievance could have an imminent and significant impact on the health or safety of the participant.

(i) *Grievance resolution notification.* The PACE organization must inform the individual who submitted the grievance of the resolution as follows:

(1) Either orally or in writing, based on the individual's preference for notification, except for grievances identified in paragraph (i)(3) of this section.

(2) At a minimum, oral or written notification of grievance resolutions must include the following, if applicable:

(i) A summary statement of the participant's grievance including all distinct issues.

(ii) For each distinct issue that requires an investigation, the steps taken to investigate the issueand a summary of the pertinent findings or conclusions regarding the concerns for each issue.

(iii) For a grievance that requires corrective action, the corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur.

(3) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must describe the right of a Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. For any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint.

(4) The PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive the notification, and the PACE organization has documented this request in writing. The PACE organization is still responsible for paragraphs (i)(1) through (3) of this section.

(j) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(k) *Maintaining confidentiality of grievances.* The PACE organization must develop and implement procedures to maintain the confidentiality of a grievance, including protecting the identity of all individuals involved in the grievance from other employees and contractors when appropriate.

(l) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. These records, except for information deemed confidential as a part of paragraph (k) of this section,, must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

(m) *Analyzing grievance information.* The PACE organization must aggregate and analyze the information collected under paragraph (l) of this section for purposes of its internal quality improvement program.

§ 460.121 [Amended]

■ 110. Section 460.121 is amended in paragraph (i)(2) by adding the phrase ''either orally or'' after the phrase ''their designated representative''.

■ 111. Section 460.198 is added to subpart K to read as follows:

§ 460.198 Disclosure of compliance deficiencies.

CMS may require a PACE organization to disclose to its PACE participants or potential PACE participants, the PACE organization's performance and contract compliance deficiencies in a manner specified by CMS.

■ 112. Section 460.200 is amended by revising paragraph (d)(2) to read as follows:

§ 460.200 Maintenance of records and reporting of data.

* * * * *

(d) * * *

(2) Maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant's care, health, or safety 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, care, health, or safety.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

* * * * *

§ 460.202 [Amended]

■ 113. Section 460.202 is amended in paragraph (b) by removing the last sentence.

■ 114. Section 460.210 is amended by revising paragraph (b)(6) to read as follows:

§ 460.210 Medical records.

* * * * *

(b) * * *

(6) Original documentation, or an unaltered electronic copy, of any written communication as described in § 460.200(d)(2) must be maintained in the participant's medical record unless the following requirements are met:

(i) The medical record contains a thorough and accurate summary of the communication including all relevant aspects of the communication,

(ii) Original documentation of the communication is maintained outside of the medical record and is accessible by employees and contractors of the PACE organization when necessary, and in accordance with § 460.200(e), and

(iii) Original documentation of the communication is available to CMS and the SAA upon request.

* * * * *

Title 45

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 115. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

■ 116. Section 170.205 is amended by revising paragraphs (b)(1) and (2) and adding paragraph (c) to read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * * *

(b) * * *

(1) *Standard.* National Council for Prescription Drug Programs (NCPDP): SCRIPT Standard Implementation Guide; Version 2017071 (incorporated by reference in § 170.299). The Secretary's adoption of this standard expires on January 1, 2025.

(2) *Standard.* NCPDP SCRIPT Standard, Implementation Guide, Version 2022011 (incorporated by reference in § 170.299).

(c) *Real-Time Prescription Benefit* —(1) *Standard.* NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12 (incorporated by reference in § 170.299).

(2) [Reserved]

* * * * *

■ 117. Section 170.299 is amended by revising paragraphs (a) and (k) to read as follows:

§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services (HHS) must publish a document in the **Federal Register** and the material must be available to the public. All approved incorporation by reference (IBR) material is available for inspection at the HHS and at the National Archives and Records Administration (NARA). Contact HHS at: U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201; call ahead to arrange for inspection at 202–690–7151. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.* The material may be obtained from the sources in the following paragraphs of this section.

* * * * *

(k) National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; phone (480) 477–1000; fax: (480) 767–1042: website: *www.ncpdp.org.* (1) SCRIPT Standard, Implementation Guide, Version 2017071 (Approval Date for ANSI: July 28, 2017), IBR approved for § 170.205(b).

(2) NCPDP SCRIPT Standard, Implementation Guide, Version 2022011, January 2022, (Approval Date for ANSI: December 2, 2021), IBR approved for § 170.205(b).

(3) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12, October 2021 (Approval Date for ANSI: September 27, 2021), IBR approved for § 170.205(c).

* * * * *

Dated: December 7, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–26956 Filed 12–14–22; 4:15 pm]

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Part III

Department of Transportation

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 110, 171, et al.
Hazardous Materials: Editorial Corrections and Clarifications; Final Rule

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 110, 171, 172, 173, 174, 175, 176, 177, 178, and 180

[Docket No. PHMSA–2021–0091 (HM–260B)]

RIN 2137–AF56

Hazardous Materials: Editorial Corrections and Clarifications

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule corrects editorial errors and improves the clarity of certain provisions in PHMSA's program and procedural regulations and in the Hazardous Materials Regulations. The intended effect of this rulemaking is to enhance accuracy and reduce misunderstandings of the regulations. The amendments contained in this final rule are non-substantive changes and do not impose new requirements.

DATES: This final rule is effective January 26, 2023.

FOR FURTHER INFORMATION CONTACT: Yul B. Baker Jr., Standards and Rulemaking Division, at (202) 366–8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, East Building, 2nd Floor, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

The Pipeline and Hazardous Materials Safety Administration (PHMSA), in this final rule, is amending the Hazardous Materials Regulations (HMR; 49 Code of Federal Regulations (CFR) parts 171–180) to correct typographical errors; fix incorrect regulatory references and citations; remove obsolete references to regulatory provisions, dates, as well as outdated concepts such as other regulated materials-domestic (ORM–D); address misstatements of certain regulatory requirements; and supply information or language that had been inadvertently omitted. Further, within the scope of this rulemaking, PHMSA is revising certain procedural regulations at 49 CFR parts 107 and 110 to make them easier to understand. PHMSA expects the regulatory amendments adopted in this final rule will ensure stakeholders focus their resources on compliance with pertinent safety requirements of the HMR rather than trying to resolve erroneous, ambiguous, or obsolete language within PHMSA's regulations.

The amendments contained in this final rule are non-substantive changes that do not impose new requirements that necessitate public comment. The final rule's amendments are consistent with PHMSA's historical practice of regularly reviewing the HMR and PHMSA's program and procedural regulations for opportunities to eliminate regulatory confusion, fix typographical errors and omissions, and remove obsolete material and references.

II. Removing Outdated References to Other Regulated Materials-Domestic (ORM–D)

In 2011, PHMSA published final rule HM–215K [1] in which PHMSA amended the HMR to maintain alignment with updates to certain international standards and regulations. Among these amendments, PHMSA adopted changes to align existing limited quantity provisions with the global system of transport of limited quantity material under international standards and regulations including the International Maritime Dangerous Goods (IMDG) Code, the International Civil Aviation Organization's (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air, and the United Nations (UN) Recommendations on the Transport of Dangerous Goods—Model Regulations. These changes included the phase-out of existing provisions in the HMR for limited quantities reclassed as ORM–D (*e.g.,* limited quantity material defined as consumer commodities). This shift allowed for the use of a single global system for the transportation of limited quantities of hazardous materials and would transition shipments within the United States away from the domestic provisions for ORM–D reclassification and marking for certain limited quantity hazardous materials. Specifically, PHMSA adopted sunset dates for use of the domestic ORM–D classification and associated package marking ''Consumer commodity, ORM–D.'' Hazardous materials transported by air had an implementation date of January 1, 2013, and hazardous materials transported by all other modes had an implementation date of January 1, 2014.

In response to appeals to final rule HM–215K,[2] PHMSA extended the authorized use of the ORM–D classification and packages marked ''Consumer commodity, ORM–D'' for domestic highway, rail, and vessel transportation until December 31, 2020, to allow sufficient time for domestic shippers and carriers to adjust to this revised global system of transporting limited quantity materials. Since this phase-out period has passed—and use of the ORM–D classification is no longer authorized—PHMSA is removing any reference to ORM–D from the HMR in the following locations:

- Appendix A to Subpart D of Part 107—Guidelines for Civil Penalties (List of Frequently Cited Violations)
- § 171.8—In the definition of ''Agricultural product''
- § 172.101(f)
- § 172.101—deletion of Hazardous Materials Table (HMT) entries: ''Cartridges power device (used to project fastening devices), ORM–D,'' ''Cartridges, small arms, ORM–D,'' and ''Consumer commodity, ORM–D.''
- § 172.102(c)(1)—deletion of Special Provision 222
- § 172.200(b)(3)
- § 172.315(d)
- § 172.316
- § 172.500(b)(2)
- § 172.504—Table 2
- § 172.512(c)
- § 172.600(d)
- § 173.2—Hazardous Material Classes and Index to Hazard Classifications
- § 173.6(a)(1) introductory text and (a)(1)(ii)
- § 173.12(h) introductory text, (h)(1) and (h)(3)
- § 173.24a(c)(1)(iii)
- § 173.27—Table 3
- § 173.29(b)(2)(iv)(A)
- § 173.36(h)(1)(iii)
- § 173.63(b)(1)(ii), (b)(1)(iii) introductory text, and (b)(2) introductory text
- § 173.144
- § 173.145
- § 173.150(c)

[1] 76 FR 3308 (Jan. 19, 2011).

[2] 78 FR 1101 (Jan. 7, 2013).

- § 173.151(c)
- § 173.152(c)
- § 173.153(c)
- § 173.154(c)
- § 173.155(c)
- § 173.156(b), (b)(2), and (d)
- § 173.161(d)(2)
- § 173.165(d)
- § 173.230(h)
- § 173.306(a)(1), (b), (h)(2)(i), (i)(1), and (i)(2)
- § 174.82(a)
- § 176.11(e)

III. Updating Titles to Subpart B of Part 177

In part 177, subpart B—Loading and Unloading, some of the regulatory provision titles in the subpart reference the hazard class with a descriptive term while other titles reference only the hazard class number (*e.g.,* Class 8 (corrosive) materials vs Class 1 materials). For consistency and uniformity within subpart B, PHMSA amends the titles to include a descriptive term associated with the hazard class in the following sections:

- § 177.835—Class 1 (explosive) materials
- § 177.837—Class 3 (flammable liquid and combustible liquid) materials
- § 177.841—Division 6.1 (poisonous) materials and Division 2.3 (poisonous gas) materials

IV. Section-by-Section Review of Changes

In addition to the specific changes noted in ''Section II. Removing Outdated References to Other Regulated Materials-Domestic (ORM–D),'' the following is a section-by-section summary of the editorial corrections and clarifications made in this final rule. PHMSA is also making minor technical corrections throughout the HMR to align cross-references with current regulatory requirements and provisions.

A. Part 107

Section 107.109

This paragraph provides the requirements to apply for the renewal of a special permit. In paragraph (a)(4) of § 107.109, a person must include a certification that the original application, as updated by any application for renewal, remains accurate. PHMSA provides examples, in parentheses, of information that must be certified by a person for the renewal of a special permit application (*e.g.,* all section references, shipping description, etc.). To clarify additional information a person must certify, PHMSA revises paragraph (a)(4) by including ''email address'' among the information that must be accurate before submitting a renewal application for a special permit. Certifying an accurate email address will allow for a timely response from PHMSA and avoid unnecessary delays in the special permit renewal process.

Section 107.502

This section provides the general registration requirements for cargo tanks and cargo tank motor vehicles. In § 107.502(d), PHMSA is revising the Federal Motor Carrier Safety Administration (FMCSA) Hazardous Materials Division designation ''MC–ECH'' to read ''MC–SEH.'' PHMSA is also revising the FMCSA mailing address for registration statements to remove redundant reference to the division designation within the address.

B. Part 110

Section 110.7

This section provides the Office of Management and Budget (OMB) control number assigned to each collection of information. In final rule HM–209A,[3] PHMSA revised the HMR to align with OMB's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 200), as well as new requirements outlined in the Fixing America's Surface Transportation Act of 2015 (Pub. L. 114–94). In HM–209A, PHMSA removed and reserved §§ 110.70, 110.80, and 110.90 to eliminate duplicative language found in 2 CFR part 200. However, PHMSA did not make an accompanying revision to § 110.7, which still contains the now reserved sections. Therefore, PHMSA is removing the reference to the reserved sections currently found in § 110.7.

C. Part 171

Section 171.6

This section provides the OMB control numbers assigned to collections of information within the HMR. In final rule HM–251,[4] PHMSA requested a new information collection under OMB Control No. 2137–0628 titled ''Flammable Hazardous Materials by Rail Transportation.'' PHMSA inadvertently left out OMB control number 2137–0628 from the § 171.6(b)(2) table, and therefore, PHMSA is adding the missing control number, title, and reference sections, as appropriate, for full transparency of authorized HMR information collections.

Section 171.7

This section lists material incorporated by reference into the HMR. In final rule HM–215N,[5] PHMSA amended the HMR to maintain consistency with international regulations and standards by harmonizing with changes made to the IMDG Code, the ICAO Technical Instructions, and the UN Model Regulations. However, PHMSA made a typographical error that incorrectly changed the publication date for the referenced edition of the International Organization for Standardization standard ''ISO 4706:2008(E).'' The publication date was inadvertently changed from ''2008–04–15'' as presented in the notice of proposed rulemaking (NPRM) for HM–215N[6] to ''2008–07–014,'' which is incorrect. PHMSA is correcting this error to accurately reflect the ISO publication date of the version incorporated by reference to read: ''ISO 4706:2008(E), Gas cylinders—Refillable welded steel cylinders—Test pressure 60 bar and below, First Edition, 2008–04–15, Corrected Version, 2008–07–01'' into § 178.71.

In final rule HM–224B[7] and in consultation with the Federal Aviation Administration (FAA), PHMSA amended the HMR to authorize the use of Air Transport Association Specification 300 for Type I (ATA 300) shipping containers. Because of extensive testing and research, PHMSA eliminated special provision ''A52'' and relocated ''Oxygen, compressed'' packaging requirements from one or more of §§ 173.168(d), 173.302(f)(3), and 173.304(f)(3). However, PHMSA did not list these sections in § 171.7(b) in association with the ATA 300 standard incorporated by reference. Therefore, PHMSA is revising § 171.7(b)(1) ''ATA Specification No. 300 Packaging of Airline Supplies, Revision 19, July 31, 1996'' to include a reference to §§ 173.168(d), 173.302(f)(3), and 173.304(f)(3). In addition, PHMSA includes a cross-reference to § 171.7 within each of those same sections.

Finally, PHMSA was notified by the Compressed Gas Association (CGA) that their address in § 171.7(n) was outdated. As such, PHMSA is amending the address from ''1235 Jefferson Davis Highway, Arlington, VA 22202'' to ''8484 Westpark Drive, Suite 220, McLean, VA 22102'' per CGA's request.

[3] 84 FR 3993 (Feb. 14, 2019).
[4] 80 FR 26643 (May 8, 2015).
[5] 82 FR 15796 (Mar. 30, 2017).
[6] 81 FR 61741 (Sep. 7, 2016).
[7] 72 FR 4442 (Jan. 31, 2007).

Section 171.8

This section provides definitions and abbreviations used within the HMR. In final rule HM–215K,[8] PHMSA revised the definition of ''Oxidizing gas,'' but the outdated definition inadvertently remains in this section as a duplicate definition that is a source of confusion. Therefore, PHMSA is removing the outdated first definition of ''Oxidizing gas'' listed in the section to avoid any confusion on the applicable definition and thereby, enhancing safety for the regulated community. The version being removed reads: ''*Oxidizing gas* means a gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.''

Section 171.12

This section provides requirements specific to North American shipments of hazardous materials. Paragraph (b) of the section addresses shipments to or from Mexico. Moreover, paragraph (b) sets out specific requirements for shipments of material poisonous by inhalation (PIH). In § 171.12(b)(4), there is a reference to nonexistent paragraph (e)(5). Current paragraph (b)(4) reads that packages of PIH material are to be labeled and placarded as POISON GAS or POISON INHALATION HAZARD in accordance with the HMR, except as provided in (e)(5); and current paragraph (b)(5) indicates a label or placard conforming to the UN Model Regulations may be substituted for a POISON GAS or POISON INHALATION HAZARD label or placard. In final rule HM–215F,[9] PHMSA revised and consolidated provisions applying to North American shipments, which, in part, redesignated previous paragraphs (e)(1) through (e)(5) as paragraphs (b)(1) through (b)(5). However, in HM–215F, PHMSA did not make a conforming amendment to revise the reference to previous paragraph (e)(5) to redesignated (b)(5). Thus, PHMSA will change the paragraph reference from ''(e)(5)'' to ''(b)(5)'' to appropriately reference the alternative way to label or placard a PIH package.

Section 171.15

This section provides the requirements for the immediate notice of certain hazardous materials incidents. In § 171.15(a), PHMSA is revising this paragraph by removing the URL link to *http://www.nrc.uscg.mil* as it is no longer a valid resource for reporting hazardous material incidents. As revised, § 171.15 would require persons to instead contact the National Response Center hotline at 1–800–424–8802.

D. Part 172

Section 172.101

This section contains the Hazardous Materials Table (HMT) and explanatory text for each of the columns in the table. In this final rule, PHMSA is amending the HMT explanatory text as described below:

- Section 172.101(f) addresses column (5) of the HMT for assignment of the packing group and explains that certain Classes and Divisions of hazardous materials are not assigned packing groups. This includes Division 6.2 materials other than Division 6.2 regulated medical wastes. However, in final rule HM–215P,[10] PHMSA removed the assignment of PG II in column (5) for the hazardous materials description ''UN3291, Regulated medical waste, n.o.s. *or* Clinical medical waste, unspecified, n.o.s. *or* (BIO) Medical waste, n.o.s. *or* Biomedical waste, n.o.s., *or* Medical Waste n.o.s.'' creating an inconsistency with the text in § 172.101(f). Accordingly, PHMSA is revising the second sentence of § 172.101(f) by deleting the parenthetical text ''(other than regulated medical wastes)'' to remove any possible misunderstanding that Division 6.2 regulated medical wastes are not assigned a packing group and thus removing a source of confusion whether to indicate the packaging group on a shipping paper for regulated medical waste.
- In final rule HM–218C,[11] PHMSA amended the HMR by adopting miscellaneous changes based on petitions for rulemaking and PHMSA initiatives. In HM–218C, PHMSA amended § 172.101(i)(3) by adding a statement to clarify that some bulk packaging authorizations are found in column (8B) and the special provisions in column (7) of the HMT. However, PHMSA inadvertently removed subparagraphs (i–iii) from § 172.101(i)(3); therefore, PHMSA will add the subparagraphs back to this section.

Additionally, PHMSA is making corrections to information in the HMT as follows:

Column 1—Symbol Changes

- PHMSA is correcting an inadvertent deletion of the ''G'' symbol for the following entries: ''UN2920, Corrosive liquid, self-heating, n.o.s., 8, PG I,'' ''UN2921, Corrosive solids, flammable, n.o.s., 8, PG I,'' and ''UN2925, Flammable solids, corrosive, organic, n.o.s., 4.1, PG II'' by adding the ''G'' symbol for these entries. The assignment of a ''G'' identifies a proper shipping name (PSN) for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description (*i.e.,* with the UN identification number, the PSN, the hazard class, and the packing group). These HMT entries are n.o.s. PSNs and as defined in § 171.8, ''N.O.S.'' means not otherwise specified. Because they do not specify a technical name for the hazardous material, n.o.s. PSNs are typically assigned ''G'' in column (1).

Column 2—PSN Changes

- PHMSA is correcting an inadvertent typo where the language in italics for ''UN1263, Paint *including paint, lacquer, enamel, stain, shellac solutions, varnish, polish, liquid filler and liquid lacquer base*'' is missing a set of parentheses to indicate the language in italics is not a part of the PSN. PHMSA is correcting this error by including a parenthesis before the word ''including'' and after the word ''base.''
- In final rule HM–219C,[12] PHMSA amended the HMR in response to petitions for rulemaking. HM–219C revised the transportation requirements for limited quantity shipments of hydrogen peroxide including revising the HMT entries to harmonize the limited quantity exceptions with the ICAO Technical Instructions and the UN Model Regulations. For ''UN2014, Hydrogen, peroxide, aqueous solutions with more than 40 percent, but not more than 60 percent hydrogen peroxide (stabilized as necessary), 5.1, PG II'' and ''UN2014, Hydrogen peroxide, aqueous solutions with not less than 20 percent, but not more than 40 percent hydrogen peroxide (stabilized as necessary), 5.1, PG II,'' the HMT entries do not display the correct PSN. The language ''with more than 40 percent, but not more than 60 percent hydrogen peroxide (stabilized as necessary)'' and ''with not less than 20 percent, but not more than 40 percent hydrogen peroxide (stabilized as necessary),'' respectively, is displayed in Roman type font making it appear that the text is part of the PSN. This is incorrect. The PSN is ''Hydrogen peroxide, aqueous solutions'' and the remainder of the language should be italicized. As instructed in § 172.101(c)(1), words in italics are not part of the PSN, but may be used in addition to the PSN. Therefore, PHMSA

[8] 76 FR 3308 (Jan. 19, 2011).

[9] 72 FR 25161 (May 3, 2007).

[10] 87 FR 44944 (Jul. 26, 2022).

[11] 70 FR 34066 (Jun. 13, 2005).

[12] 85 FR 75680 (Nov. 25, 2020).

is correcting this error to italicize the additional text.

• For ''UN3021, Pesticides, liquid, flammable, toxic, flash point less than 23 degrees C,'' the PSN as well as the explanatory text regarding the flash point of the material is displayed in Roman type font. In final rule HM–215M,[13] PHMSA inadvertently revised the italic font of the explanatory text for ''UN3021'' when the stowage code assigned in the HMT for this entry was updated. By not having the explanatory text in italics, the whole description reads as the PSN. Therefore, PHMSA is amending the ''UN3021 entry to the following: ''UN3021, Pesticides, liquid, flammable, toxic, *flash point less than 23 degrees C.*''

• For ''UN3321, Radioactive material, low specific activity (LSA–III) non fissile or fissile-excepted,'' the explanatory text regarding non fissile or fissile-excepted is displayed in Roman type font, making the text part of the PSN, which is not the intent. In HM–215O,[14] PHMSA inadvertently revised the italic font for ''non fissile or fissile-excepted'' when the table entry for ''UN3321'' was updated to reflect the addition of special provision 325. Therefore, PHMSA is amending the ''UN3321'' entry to the following: ''UN3321, Radioactive material, low specific activity (LSA–III) *non fissile or fissile-excepted*.''

• PHMSA is correcting a typographical error where the language in the HMT shows the term ''wheel chair'' as two separate words, which is incorrect. To clarify and to eliminate confusion, the term should be one word and spelled as ''wheelchair'' instead.

Column 6—Label Code Changes

• In final rule HM–215P, the proper shipping name for ''UN3363, Dangerous Goods in Machinery *or* Dangerous Goods in Apparatus, 9,'' was revised to the following: ''UN3363, Dangerous goods in articles *or* Dangerous goods in machinery *or* Dangerous goods in apparatus, 9.'' This PSN revision is reflected in the current UN Model Regulations. In making this revision to the PSN, PHMSA mistakenly deleted the label code in column (6) for this table entry. Therefore, PHMSA is correcting this error by adding label code ''9'' back to column (6) to indicate a Class 9 label is required for this material.

Column 7—Special Provision Changes

• In final rule HM–233F,[15] PHMSA added special provision 383 in association with adopting DOT special permit (DOT–SP) 11356 into the HMR, which authorized a material meeting the conditions for high viscosity flammable liquids specified in § 173.121(b)(1)(i), (b)(1)(ii), and (b)(1)(iv), to be re-classed to PG III for transportation by motor vehicle. However, PHMSA inadvertently did not add the new special provision to the following HMT entries: ''UN1139, Coating solution *(includes surface treatments or coatings used for industrial or other purposes such as vehicle undercoating, drum or barrel lining),* 3, PG II'' and ''UN1263, 3, PG II'' even though these materials were covered in DOT–SP 11356. PHMSA is correcting this omission by adding special provision 383 to HMT entries ''UN1139'' and ''UN1263'', respectively.

• In final rule HM–215P, PHMSA amended the regulations to allow ''UN2216, Fish meal, stabilized *or* Fish scrap, stabilized, 9, PGIII,'' to be transported by passenger and cargo aircraft subject to specific quantity limitations for the material. When PHMSA proposed the changes to this table entry, we did not propose removal of special provision ''B136'' from column (7) nor did we propose to remove the word ''None'' from column (6), yet we mistakenly deleted special provision ''B136'' and the word ''None.'' Therefore, PHMSA is correcting this error by adding special provision ''B136'' back to column (7) and the word ''None'' back to column (6).

• For ''UN3084, Corrosive solids, oxidizing, n.o.s., PG II,'' there is a typographical error where special provision 154 is listed in column 7, but there is no such special provision in § 172.102. Therefore, PHMSA is removing ''154'' from column 7.

• In final rule HM–259,[16] PHMSA removed special provision A6, which provided methods of packaging liquid hazardous material for air transport, from certain HMT entries. Specifically, PHMSA removed the assignment of A6 from liquid hazardous material. However, in HM–219C, special provision A6 was inadvertently reassigned to some of the entries from which they were originally removed. Therefore, PHMSA is correcting this by again removing assignment of special provision A6 from the following:

○ ''UN1111, Amyl mercaptan, 3, PG II''

○ ''UN1228, Mercaptans, liquid, flammable, toxic, n.o.s. *or* Mercaptan mixtures, liquid, flammable, toxic, n.o.s., 3, PG III''

○ ''UN1732, Antimony pentafluoride, 8, PG II''

○ ''UN1768, Difluorophosphoric acid, anhydrous, 8, PG II''

○ ''UN1776, Fluorophosphoric acid anhydrous, 8, PG II''

○ ''UN1778, Fluorosilicic acid, 8, PG II''

○ ''UN1782, Hexafluorophosphoric acid, 8, PG II''

○ ''UN1808, Phosphorus tribromide, 8, PG II''

○ ''UN2031, Nitric acid *other than red fuming, with at least 65 percent, but not more than 70 percent nitric acid,* 8, PG II''

○ ''UN2031, Nitric acid *other than red fuming, with more than 20 percent and less than 65 percent nitric acid,* 8, PG II''

○ ''UN2031, Nitric acid *other than red fuming, with not more than 20 percent nitric acid,* 8, PG II''

○ ''UN2258, 1,2-Propylenediamine, 8, PG II''

○ ''UN2734, Amine, liquid, corrosive, flammable, n.o.s. *or* Polyamines, liquid, corrosive, flammable, n.o.s., 8, PG I''

○ ''UN2920, Corrosive liquids, flammable, n.o.s., 8, PG I''

○ ''UN3093, Corrosive liquids, oxidizing, n.o.s., 8, PG I''

○ ''UN3093, Corrosive liquids, oxidizing, n.o.s., 8, PG II''

○ ''UN3098, Oxidizing liquid, corrosive, n.o.s., 5.1, PG I''

○ ''UN3149, Hydrogen peroxide and peroxyacetic acid mixtures, stabilized *with acids, water, and not more than 5 percent peroxyacetic acid,* 5.1, PG II''

○ ''UN2014, Hydrogen peroxide, aqueous solutions *with not less than 20 percent, but not more than 40 percent hydrogen peroxide (stabilized as necessary),* 5.1, PG II''

• For ''UN1740, Hydrogendifluoride, solid, n.o.s., 8, PG III,'' PHMSA is correcting an error where special provisions 53 and 58 are missing from column 7.

• For ''UN1783, Hexamethylenediamine solution, 8, PG III, PHMSA is correcting an error where special provision 52 is missing from column 7.

Column 8—Packaging Authorization Changes

• In column (8B) for ''UN2734, Amine, liquid, corrosive, flammable, n.o.s. *or* Polyamines, liquid, corrosive, flammable, n.o.s., 8, PG II,'' the packaging instruction was inadvertently changed from ''202'' to ''201.'' To correct this error, PHMSA will revert

[13] 80 FR 1076 (Jan. 8, 2015).

[14] 85 FR 27810 (May 11, 2020).

[15] 81 FR 3636 (Jan. 21, 2016).

[16] 83 FR 52878 (Oct. 18, 2018).

the packaging instruction in column 8(B) back to ''202.'' The packagings authorized under § 173.201 are for liquid hazardous materials in PG I. Section 173.202 provides authorized packagings for liquid hazardous materials in PG II which is the correct packaging section reference for this PG II material.

Column 10—Vessel Stowage Changes

- In column (10B) for ''UN1510, Tetranitromethane, 6.1, PG I,'' there is a typographical error for one of the vessel stowage codes assigned to this material. The stowage codes as currently listed for ''UN1510'' are ''40 and 6.'' The stowage code 6 is incorrect as it is missing a ''6.'' PHMSA is amending column (10B) to reflect the correct stowage code of ''66.'' Stowage code 6 instructs that a material is an emergency temperature material, which is not relevant in the case of stowage of tetranitromethane. Stowage code 66 instructs a person to stow this material separated from flammable solids, which is consistent with IMDG Code segregation code ''SG16'' assigned to ''UN1510'' to ''stow separated from Division 4.1'' (flammable solids). This amendment will ensure that this material is properly stowed for safe transport.
- In column (10B) for ''UN2627, Nitrites, inorganic, n.o.s., 5.1, PG II,'' there is a typographical error for one of the vessel stowage codes assigned to this material. The stowage codes as listed for ''UN2627'' are ''46, 56, 58, and 13.'' Stowage code 13 is incorrect as it is missing a ''3.'' PHMSA is amending column (10B) to reflect the correct stowage code of ''133.'' Stowage code 13 instructs to keep as reasonably dry as possible, which is not relevant in the case of stowage of inorganic nitrite. Stowage code 133 instructs to stow ''separate from sulfur,'' and is thus the appropriate stowage instruction, and is consistent with § 176.400(d) as well as IMDG Code segregation code ''SG62'' assigned to ''UN2627'' to stow ''separated from'' sulfur. This amendment will ensure that this material is properly stowed for safe transport.
- In column (10B), for ''UN1788, Hydrobromic acid, *with not more than 49 percent hydrobromic acid,* 8, PG II'' and for ''UN1788, Hydrobromic acid, *with not more than 49 percent hydrobromic acid,* 8, PG III,'' stowage codes ''53'' and ''58'' are missing. Stowage code ''53'' provision means stow ''separated from'' alkaline compounds and stowage code ''58'' provision means stow ''separated from'' cyanides. In final rule HM–215O, PHMSA amended the HMR to maintain alignment with international regulations and standards by incorporating various amendments, including changes to vessel stowage requirements. Consistent with changes made to Amendment 39–18 of the IMDG Code, PHMSA made numerous changes to special stowage and segregation provisions, specifically ''Other'' provisions as indicated in column (10B). Because of these changes, ''UN1788'' for both PG II and PG III should have stowage codes ''53'' and ''58'' listed in column (10B) therefore, PHMSA is amending the HMT to reflect this inadvertent omission.

Section 172.102

This section provides a list of special provisions as referred to in Column (7) of the HMT. Regarding ''UN1408, Ferrosilicon *with 30 percent or more, but less than 90 percent silicon,* 4.3, PG III,'' it is assigned IP code [17] ''IP7'' in the HMT, yet the material (*i.e.,* the UN identification number) is not listed among the materials subject to IP7. IP codes are special provisions on the use of intermediate bulk containers (IBCs) for transport of certain hazardous materials. In final rule HM–215G,[18] the Research and Special Programs Administration (RSPA)—now PHMSA—amended the HMR to align with international standards, which included changes to special provisions. The omission from special provision IP7 was inadvertent as ''UN1408'' is listed among materials subject to the same IBC special provision as part of the IMDG Code. For clarity of understanding that IP7 applies to ferrosilicon material, PHMSA is adding ''UN1408'' to the list of UN identification numbers in IP7.

Section 172.202

This section provides the requirements to describe hazardous materials on shipping papers. In § 172.202(a)(4), there is a requirement to include the packing group (PG) [19] with the required shipping description of a hazardous material on a shipping paper. However, certain types of hazardous materials are not assigned a ''PG'' because they do not exhibit a degree of danger that needs to be communicated. For instance, batteries of all types, including lithium, lithium ion, and sodium batteries, are not assigned a ''PG'' in the HMT. In final rule HM–215M, PHMSA amended the HMR to maintain alignment with international standards, which included removing the generalized ''PG II'' assignment for lithium ion batteries, lithium metal batteries, and sodium batteries. However, the language in § 172.202(a)(4) states that ''batteries other than those containing lithium, lithium ions, or sodium'' are excepted from including a ''PG'' is a source of confusion because lithium, lithium ion, or sodium batteries are no longer assigned a ''PG'' in the HMT. Therefore, PHMSA is amending § 172.202(a)(4) by removing reference to lithium, lithium ion, and sodium batteries from this paragraph.

Section 172.203

This section provides additional description requirements for shipping papers. Section 172.203(e)(1) and (e)(2) provide instruction for the description of residue hazardous material on a shipping paper. The language to include ''residue: last contained'' reads different in the paragraphs, specifically, ''RESIDUE: Last Contained***'' in (e)(1) and ''RESIDUE: LAST CONTAINED***'' in (e)(2). For consistency, PHMSA is revising the language in (e)(2) to the following: ''RESIDUE: Last Contained.'' Additionally, consistent with § 172.101(l)(1)(ii), stocks of preprinted shipping papers may be continued in use, with the text previously required in (e)(2), until depleted or for a one-year period, after the effective date of this rule, whichever is less.

Section 172.204

This section provides the requirements for shipper's certification. In final rule HM–216B,[20] PHMSA amended the HMR to adopt provisions contained in certain widely used or longstanding rail special permits, which included revisions to the shipper certification for transportation by rail. PHMSA had received a comment from Union Pacific Railroad to revise the language in § 172.204(a)(3)(ii) to the following: ''*Electronic certification.* When transmitted electronically, by entering the name of the principal person, partner, officer, or employee of the offeror or his agent in a specific EDI.'' [21] PHMSA agreed with revising the language; and offered a revised version ''to emphasize that by completing a signature field on an EDI document, the shipper is certifying that the document complies with . . .

[17] IP codes are special provisions that apply to intermediate bulk containers.

[18] 69 FR 76044 (Dec. 20, 2004).

[19] Packing group means a grouping according to the degree of danger presented by hazardous materials. Packing Group I indicates great danger; Packing Group II, medium danger; Packing Group III, minor danger.

[20] 77 FR 37962 (Jun. 25, 2012).

[21] EDI, or electronic data interchange, as defined in § 171.8, means the computer-to-computer exchange of business data in standard formats.

§ 172.204(a).'' However, stakeholders have reported that the current language adopted in the HM–216B [22] notice of proposed rulemaking (''must be substituted for the asterisks'') is considered a source of confusion because there are neither asterisks in the certification statement in § 172.204(a) nor in typical EDI documents. To clarify this section for simplicity of understanding and consistent with final rule HM–216B, PHMSA will amend § 172.204(a)(3)(ii) to read as follows: ''Electronic Certification. When transmitted electronically, by completing the field designated for the shipper's signature with the name of the principal person, partner, officer, or employee of the offeror or their agent, the shipper is also certifying its compliance with the certification specified in § 172.204(a).'' This revision is consistent with § 172.204(d)(3) certification signature requirements for transportation by rail that requires ''the name of the principal person, partner, officer, or employee of the offeror or his agent in a computer field defined for that purpose.''

Section 172.315

This section provides the requirements for limited quantities of hazardous material. The dates for transitional exceptions in § 172.315(d) allowing limited quantity marking requirements for alternatively marked packages and ORM–D marked packages have passed. Therefore, PHMSA is deleting and reserving paragraph (d) as the transition periods no longer apply.

Section 172.332

This section provides the requirements for identification number markings. In § 172.332(d), the placard dimensions illustrated in this paragraph are incorrect. In final rule HM–218F,[23] PHMSA amended the HMR to make miscellaneous amendments to update and clarify certain regulatory requirements. To align with international standards, PHMSA authorized the use of placards measuring 250 mm (9.84 inches) on each side. However, for the example used in § 172.332(d) to illustrate the display of an identification number on a placard, the placard dimensions are not consistent with the current minimum size requirements for a placard found in § 172.519(c). Therefore, to avoid confusion PHMSA is amending § 172.332(d) by replacing the illustration with one that does not have measurements.

Section 172.400

This section provides general requirements for labeling of packages. In the table to paragraph (b), there is a typo where the word ''Oxidizer'' is misspelled as ''Oxider.'' PHMSA is correcting this misspelling by replacing it with the correct term ''Oxidizer.''

Section 172.519

This section provides the requirements for general specifications for placards. Section 172.519(c)(1)(i) currently states, ''A placard in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue to be used until December 31, 2016.'' The transitional period for this exception to use a placard that conforms to § 172.519(c)(1) requirements effective at the end of 2014 has passed. Therefore, PHMSA is amending § 172.519(c)(1) by deleting the transitional exception reference and merging what is currently in paragraphs (c)(1) introductory text and (c)(1)(ii) together.

E. Part 173

Section 173.4a

This section provides the requirements for excepted quantities of hazardous material. The § 173.4a(g)(2)(i) transitional exception from the excepted quantities marking specifications states: ''A marking in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue to be used until December 31, 2016.'' This transitional period for exception from certain marking requirements has passed. Therefore, PHMSA is amending § 173.4a(g)(2) by deleting the paragraph (g)(2)(i) transitional exception and merging what is currently in paragraphs (g)(2) introductory text and (g)(2)(ii) together.

Section 173.11

This section provides exceptions for the shipment of light bulbs containing hazardous materials. In § 173.11(b), there is a punctuation error at the end of the paragraph where a semicolon is used instead of a period to separate the standalone provisions of paragraphs (b) and (c) in this section. PHMSA is revising paragraph (b) by replacing the semicolon with a period at the end of the paragraph to clearly communicate that paragraph (b) and (c) are standalone provisions.

Section 173.25

This section provides the requirements for authorized packagings and overpacks. Section 173.25(a)(4)(i) states: ''A marking in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue to be used until December 31, 2016.'' The transitional exception period to mark an overpack has passed. Therefore, PHMSA is amending § 173.25(a)(4) by deleting this transitional exception reference and merging what is currently in paragraphs (a)(4) introductory text and (a)(4)(ii) together.

Section 173.27

This section provides the general requirements for transportation by aircraft. In HM–215P, PHMSA made numerous amendments in Table 1 and Table 2 to paragraph (f) by clarifying the inner packaging quantity limits for combination packages and added inner package limits for certain Class 9 HMT entries consistent with the ICAO Technical Instructions. When these amendments were added, PHMSA inadvertently made a change that had not been proposed for comment to the Table 2 maximum authorized net capacity of each inner packaging for transportation by cargo aircraft. Specifically, for packages containing a net quantity of solids not greater than 15 kg, PHMSA made a change to the maximum authorized net capacity for metal or plastic inner packagings. Prior to publication of HM–215P, the HMR authorized 2.5 kg consistent with the ICAO Technical Instructions. As it currently reads in the HMR, the maximum authorized net capacity of each inner packaging for metal or plastic inner packagings is 1 kg—which is incorrect—which is now a source of confusion and disharmony with international air transport regulations. Therefore, PHMSA is correcting this error by revising 1 kg back to 2.5 kg. In addition, PHMSA is removing the ''periods'' in the third column of Table 2 for consistency with the first and second columns, which do not have periods associated with the information presented in those columns.

Section 173.62

This section provides specific packaging requirements for explosives. In HM–215B,[24] RSPA amended the HMR to maintain alignment with corresponding provisions of international standards. Prior to final rule HM–215B, ''UN0485, Substances, explosive, n.o.s., 1.4G'' was included in the table and assigned packing instruction E–103 in the HMR, which required packagings to be determined by

[22] 76 FR 51324 (Aug. 18, 2011).

[23] 76 FR 43510 (Jul. 20, 2011).

[24] 87 FR 24690 (May 6, 1997).

a competent authority approval. However, RSPA inadvertently omitted this material from the revised Explosives Table. Therefore, PHMSA is amending Table 1 to Paragraph (b): Explosive Table to include an entry for ''UN0485'' and assign it packing instruction 101, requiring competent authority approval, consistent with the packing instruction assigned prior to the inadvertent omission and with international standards.

Section 173.185

This section provides the requirements for packing and hazard communication of lithium cells and batteries. The HMR includes use of the phrase ''assemblies of such batteries'' in § 173.185(b)(5) and (e)(5). However, we neither define this phrase nor does it have substantive meaning associated with the requirements for lithium batteries weighing 12 kg or more. Furthermore, use of this terminology was recently removed from the UN Model Regulations. To avoid confusion as to its intended meaning and to maintain consistency with international standards, PHMSA is amending § 173.185(b)(5) and (e)(5) by removing this language.

For § 173.185(c)(3), the title of (c)(3) ''Hazard communication,'' is no longer considered appropriate for the content of this paragraph. Paragraph (c)(3) covers the requirements for applying the lithium battery mark. Moreover, there are other hazard communication requirements that may apply besides those listed in § 173.185(c)(3), such as the requirements listed in § 173.185(c)(1)(iii) and (c)(1)(iv), which provide additional marking requirements for a lithium battery. Therefore, PHMSA is amending the title of § 173.185(c)(3) to read ''*Lithium battery mark*'' for a simpler understanding of the subject of this paragraph.

Section 173.185(d) provides limited exceptions from transportation requirements for lithium cells or batteries that are being shipped for disposal or recycling. However, the paragraph is not formatted to list each condition for exception as other similar paragraphs in the section and HMR. Therefore, to clarify the conditions for exception, PHMSA is amending § 173.185(d) by revising the paragraph to list each condition for transportation of a lithium cell or battery being shipped for disposal or recycling.

Section 173.225

This section provides packaging requirements and other provisions for organic peroxides. In final rule HM–215N,[25] PHMSA amended the HMR to maintain consistency with international regulations and standards. Specifically, to maintain consistency with UN Model Regulations, PHMSA amended several entries and corrected formatting errors in the Organic Peroxide Table in paragraph (c). As part of these revisions, the entire table was reproduced in final rule HM–215N. However, in reproducing the entire table, for many entries, the ''+'' symbol was inadvertently removed from Column 7 in the table. Column 7 specifies the control and emergency temperatures to be maintained for the listed material while it is in transportation. Without the ''+'' by the number provided in the column, a reader would be unable to determine for certain the required control and emergency temperatures. For example, for ''UN3115, tert-Amyl peroxy-2-ethylhexanoate,'' without a ''+'' in front of the ''20'' for the control temperature, one is not certain whether that is meant to be –20°C or +20°C. Therefore, PHMSA is adding the ''+'' symbol to specific entries in the table that were inadvertently removed under HM–215N to ensure clear understanding of the required control and emergency temperatures. This amendment will enhance safety by ensuring the proper control temperature is listed in the HMT.

Sections 173.244 and 173.314

This section provides the requirements for bulk packagings for certain pyrophoric liquids (Division 4.2), dangerous when wet materials (Division 4.3), and poisonous liquids with inhalation hazards (Division 6.1). Section 173.314 provides requirements for compressed gases in tank cars. In § 173.31(e)(4), which provides special requirements for use of rail tank cars for PIH material, the HMR provides a phase-out for the use of legacy tank cars where a tank car not meeting the requirements of §§ 173.244(a)(2) or (a)(3) and 173.314(c) or (d) may not be used for the transportation of PIH material. In final rule HM–219C,[26] PHMSA amended the HMR in response to petitions for rulemaking submitted by the regulated community, including a petition to adopt the phase-out date now found in § 173.31(e)(4). PHMSA revised the phase-out deadline for all non-HM–246[27] rail tank cars used for the transportation of PIH materials to December 31, 2027. However, although PHMSA adopted the phase-out date in § 173.31(e)(4), we did not include a reference to the phase-out deadline in §§ 173.244(a)(2) and 173.314(c)—Note 11 to Table 1, which has become a source of confusion. Therefore, to make clear the applicability of the phase-out date, PHMSA will make a reference to the phase-out date of December 31, 2027, in §§ 173.244(a)(2) and 173.314(c)—Note 11 to Table 1. In addition, PHMSA will make a reference in Note 11 to Table 1 regarding use of those tanks built after March 16, 2009. Finally, PHMSA is correcting grammatical and formatting issues in the § 173.314—Notes to Table 1 to paragraph (c).

Section 173.301

This section provides the general requirements for the shipment of compressed gases and other hazardous materials in cylinders, UN pressure receptacles, and spherical pressure vessels. Section 173.301(f)(5) provides instruction on when a pressure relief device is not required and specifies four options. The word ''or'' following paragraph (f)(5)(ii) and prior to (f)(5)(iii) is misplaced and should follow (f)(5)(iii) instead. Otherwise, it can be misunderstood that paragraph (f)(5)(iv) applies in addition to one of the first three options, which is not the case. Therefore, PHMSA is amending § 173.301(f)(5) by moving the word ''or'' between §§ 173.301(f)(5)(iii) and (iv) to ensure that it is understood that each option in the list is a standalone alternative compliance approach. In addition, PHMSA is correcting a typographical error in § 173.301(f)(5)(iv) where we are replacing the second ''or'' before the word ''this'' with the word ''of.''

Section 173.303

This section provides the requirements for charging cylinders with acetylene gas in solution. There is a typographical error in § 173.303(f)(1)(i) where the Euro sign ''€'' is listed after the first reference to ISO 3807:2013 instead of an uppercase ''(E).'' Therefore, PHMSA is revising this document reference to read as the following: ''ISO 3807:2013(E).''

Section 173.304a

This section provides additional requirements for the shipment of liquefied compressed gases in DOT specification cylinders. Table 1 to Paragraph (a)(2), ''Methyl acetylene-propadiene, mixtures, stabilized,'' has a maximum permitted filling density (percent) listed as ''not liquid at 130 °F,'' which is in error because the filling density requirement describes how full the cylinder may be and not whether the

[25] 82 FR 15796 (Mar. 30, 2017).

[26] 85 FR 75680 (Nov. 25, 2020).

[27] 74 FR 1769 (Jan. 13, 2009).

contents are in a liquid or gaseous state. In addition, ''Methyl acetylene-propadiene, mixtures, stabilized,'' is listed differently in the HMT as opposed to how it is listed in Table 1. In the notice of proposed rulemaking for HM–220D,[28] RSPA proposed to amend the HMR by revising the requirements for hazardous materials that are authorized to be offered for transportation in cylinders. When RSPA proposed changes to the table to § 173.304a(a)(2), ''Methyl acetylene-propadiene, mixtures, stabilized,'' was listed with the appropriate filling density instruction of ''not liquid full at 130 °F.'' However, in final rule HM–220D,[29] RSPA inadvertently changed the filling density requirement to read ''not liquid at 130 °F.'' Moreover, in the final rule, in response to appeals, HM–220D,[30] RSPA revised the filling density temperature requirements from ''54 °C (130 °F)'' to ''55 °C (131 °F)'' for uniformity purposes with other sections, but still kept the language ''Not liquid at.'' Therefore, PHMSA is amending the maximum permitted filling density instruction for ''Methyl acetylene-propadiene, mixtures, stabilized'' to read ''Not liquid full at 131 °F.'' Furthermore, for consistency with the how the entry for the material reads in the HMT, PHMSA is revising ''Methyl acetylene-propadiene, mixtures, stabilized'' to read ''Methyl acetylene and propadiene mixtures, stabilized.''

Also, in Table 1 to Paragraph (a)(2), Column 3 provides the authorized packagings for listed hazardous material. For ''Methyl mercaptan,'' there is a typographical error where the letter ''D'' is missing from the current entry ''OT–4B240.'' PHMSA is correcting this error by adding the missing letter so that the cylinder specification reads correctly as ''DOT–4B240.'' Finally, PHMSA is correcting grammatical errors in the notes to Table 1 to Paragraph (a)(2). For example, in Note 2, we are adding a period to the abbreviation for pound (lb.).

Section 173.313

This section provides the UN portable tank table for liquefied compressed gases and chemicals under pressure. In final rule HM–215G,[31] RSPA amended the HMR to maintain alignment with international standards. Specifically, the rule relocated the design and use requirements for portable tanks in liquefied compressed gases and chemical under pressure service—previously found in § 172.102(c)(7) Special Provisions—to § 173.313 ''UN Portable Tank Table for Liquefied Compressed Gases and Chemical Under Pressure.'' In its explanation of those changes, PHMSA stated, ''The table provides the maximum allowable working pressures, bottom opening requirements, and degree of filling requirements for liquefied compressed gases permitted for transport in portable tanks.'' This language is confusing because the table includes a ''minimum design pressure (in bar)'' requirement — a minimum design value distinguishable from the maximum allowable working pressure (MAWP) value. The minimum design pressure relates to the pressure the portable tank should be exposed to under normal conditions based on factors like material of construction and thickness of the material. The MAWP is the maximum pressure at which the portable tank would be allowed to function at a specific temperature and considers the design pressure. Therefore, PHMSA is amending § 173.313 introductory language by adding the term ''minimum design pressure'' in the header of the third column of the table.

Section 173.315

This section provides the requirements for compressed gases in cargo tanks and portable tanks. In final rule HM–245,[32] PHMSA adopted the provisions of DOT–SP 13341 into the HMR, which allowed storage containers (of 500 gallons or less water capacity) intended to be permanently installed on a consumer's premises to be transported charged with liquefied petroleum gas (LPG) in quantities greater than five percent of the container's water capacity. Furthermore, the special permit authorized one-way transportation only from the consumer's location to the container owner's nearest LPG facility. In HM–245, PHMSA revised paragraph (j) to allow these designated storage containers under specific conditions. However, PHMSA mistakenly created § 173.315(j)(3) which states: ''Storage containers of less than 1,042 pounds water capacity (125 gallons) may be shipped when charged with liquefied petroleum gas in compliance with DOT filling density.'' This specific language should have been one of the conditions under § 173.315(j)(1), and not a standalone provision as (j)(3). Therefore, PHMSA is amending § 173.315(j) by redesignating paragraph (j)(3) as paragraph (j)(1)(iv) and removing and reserving § 173.315(j)(3).

F. Part 174

Section 174.5

This section provides the requirements for a rail carrier's materials and supplies. In the second sentence, it states: ''The requirements of this subchapter do not apply to railway torpedoes or fusees when carried in engines or rail cars.'' The use of the term ''fusees'' is an industry term used to describe railroad safety flares. For simplicity and understanding of what a fusee is, PHMSA is revising the second sentence, to read as follows, ''The requirements of this subchapter do not apply to railway torpedoes or railroad safety flares (*i.e.,* fusees) when carried in engines or rail cars.''

Section 174.55

This section provides general handling and loading requirements by rail. In § 174.55(a)—specifically, regarding the last sentence providing examples of blocking and bracing in freight containers and transport vehicles—PHMSA had intended to amend this section in final rule HM–218F [33] by removing reference to the Bureau of Explosives (BOE) Pamphlet Nos. 6 and 6C and to replace them with ''the Intermodal Loading Guide for Products in Closed Trailers and Containers'' as is listed in Table 1 to § 171.7—Materials Not Incorporated by Reference. However, only the reference to BOE Pamphlet No. 6C was removed and the reference to BOE Pamphlet No. 6 remains. Furthermore, § 171.19 states ''Effective December 31, 1998, approvals or authorizations issued by the Bureau of Explosives (BOE), other than those issued under part 179 of this subchapter, are no longer valid.'' Any reference to BOE Pamphlet Nos. 6 and 6C should have been removed from § 174.55(a). For consistency and to avoid confusion, PHMSA is removing the reference to BOE Pamphlet No. 6 in paragraph (a) as well as the ''IBR'' reference because the intermodal loading guide is not a material incorporated by reference. The last sentence of the paragraph is revised to read the following: ''For examples of blocking and bracing in freight containers and transport vehicles, see the Intermodal Loading Guide for Products in Closed Trailers and Containers (see Table 1 to § 171.7 of this subchapter).''

[28] 63 FR 58460 (Oct. 30, 1998).

[29] 67 FR 51625 (Aug. 8, 2002).

[30] 68 FR 24653 (May 8, 2003).

[31] 69 FR 76044 (Dec. 20, 2004).

[32] 76 FR 5483 (Feb. 1, 2011).

[33] 76 FR 43510 (Jul. 20, 2011)

Section 174.67

This section provides the requirements for transloading operations by rail. The second sentence of § 174.67(a)(3) states in reference to securing access to railroad track: ''This requirement may be satisfied by lining each switch providing access to the unloading area against shifting and securing each switch with an effective locking device, or by using derails, portable bumper blocks, or other equipment that provides an equivalent level of safety.'' Use of the term ''shifting'' (as it applies to packages shifting in a freight container) in the context of securing access to the track has been a source of confusion among stakeholders. In final rule HM–260A,[34] PHMSA amended the HMR by clarifying the use of the term ''movement'' which, by definition in § 171.8, means the physical transfer of a hazardous material from one geographical location to another by rail, car, aircraft, motor vehicle, or vessel. Moreover, PHMSA explained that the term ''movement'' was not used appropriately regarding train securement and the safe handling or stowage of packages. PHMSA revised each instance of ''movement'' to either ''shifting'' or ''motion'' (as it applies to motion of rail cars on a track) where appropriate. However, when making changes to § 174.67(a)(3) in HM–260A, PHMSA inadvertently replaced the term ''movement'' with ''shifting'' instead of replacing the term ''movement'' with ''motion'' as explained in the discussion section ''Clarifying the Use of the Term ''Movement'' Within the HMR.'' Therefore, PHMSA is correcting this error by replacing the term ''shifting'' with the term ''motion'' to accurately represent the securement of the train on a rail track.

Section 174.101

This section provides the requirements for loading Class 1 (explosive) materials by rail. Section 174.101(h) provides instruction that for recommended methods of blocking and bracing, to see Bureau of Explosives Pamphlets No. 6 and 6A. PHMSA no longer recognizes these BOE pamphlets as sources for blocking and bracing methods for rail transportation, but instead references ''The Intermodal Loading Guide for Products in Closed Trailers and Containers'' listed in Table 1 to § 171.7—Materials Not Incorporated by Reference. Therefore, to ensure appropriate reference to blocking and bracing methods for safe rail transport, PHMSA is amending this section by removing the reference to BOE Pamphlet Nos. 6 and 6A in paragraph (h) and revising the third sentence to read as follows: ''For recommended methods of blocking and bracing, see the Intermodal Loading Guide for Products in Closed Trailers and Containers (see Table 1 to § 171.7 of this subchapter).''

Section 174.112

This section provides the requirements for loading Division 1.3 and Division 1.2 explosive materials by rail. In § 174.112(b), the last sentence of the paragraph states: ''For recommended methods of blocking and bracing see Bureau of Explosives Pamphlet No. 6.'' This reference is incorrect as PHMSA no longer recognizes this pamphlet. Rather, the recommended methods for blocking and bracing when transported by rail are in ''The Intermodal Loading Guide for Products in Closed Trailers and Containers,'' which is listed in Table 1 to § 171.7—Materials Not Incorporated by Reference. Therefore, PHMSA is amending paragraph (b) by removing the reference to BOE Pamphlet No. 6 and revising the last sentence to the following: ''For recommended methods of blocking and bracing see the Intermodal Loading Guide for Products in Closed Trailers and Containers (see Table 1 to § 171.7 of this subchapter).'' This amendment will ensure safe rail transport through recognized and recommended blocking and bracing methods.

Section 174.115

This section provides the requirements for loading Division 1.4 (explosive) material by rail. In § 174.115(a), the last sentence of the paragraph states: ''For methods of recommended loading and bracing see Bureau of Explosives Pamphlet No. 6.'' This reference is incorrect as PHMSA no longer recognizes this pamphlet. The methods for loading and bracing when transported by rail are located in ''The Intermodal Loading Guide for Products in Closed Trailers and Containers,'' which is listed in Table 1 to § 171.7—Materials Not Incorporated by Reference. Therefore, PHMSA is removing the reference to BOE Pamphlet No. 6 in paragraph (a) and revising the last sentence of the paragraph to the following: ''For methods of recommended loading and bracing see the Intermodal Loading Guide for Products in Closed Trailers and Containers (see Table 1 to § 171.7 of this subchapter).'' This amendment will ensure safe rail transport through use of recognized and recommended methods of blocking and bracing.

Section 174.290

This section provides the requirements for the rail transportation of materials extremely poisonous by inhalation shipped by, for, or to the Department of Defense. Section 174.290(h), references Sketch 1 in BOE Pamphlet No. 6. However, BOE Pamphlet No. 6 is no longer recognized by PHMSA as a valid source ''not incorporated by reference'' in § 171.7. Therefore, PHMSA is deleting reference to Sketch 1 to avoid confusion that BOE Pamphlet 6 is a source for proper methods of loading and bracing in paragraph (h).

Also, § 174.290(i), references Sketch 1 in BOE Pamphlet No. 6A. However, BOE Pamphlet No. 6A is also no longer recognized by PHMSA. Therefore, PHMSA is deleting the reference to Sketch 1 to avoid confusion that BOE Pamphlet 6A is a resource for proper methods of protecting doorways in paragraph (i).

G. Part 175

Section 175.1

This section provides the purpose, scope, and applicability of the HMR for the transportation of hazardous materials in commerce aboard an aircraft. There is a grammatical error in the section title in that a comma is missing after the word ''scope.'' Additionally, in the first sentence of paragraph (a), the word ''the'' is missing before the word ''requirements'' and the word ''an'' is missing before the word ''aircraft.'' Therefore, for improved readability and grammar, PHMSA is revising the title to § 175.1 and revising paragraph (a) to correct these errors. Additionally, there is an error in the second sentence of paragraph (b) where the first use of the term ''subchapter'' is incorrect in referencing applicability to persons performing functions subject to the subchapter. The term ''part'' should be used instead as in ''this part (*i.e.,* part 175—Carriage by Aircraft) applies to any person who performs, attempts to perform, or is required to perform any function subject to this subchapter.'' Therefore, in the second sentence of paragraph (b), PHMSA is replacing the first use of ''subchapter'' with ''part.''

Section 175.9

This section provides the requirements for special aircraft operations. There is a typographical error in the first sentence of paragraph (a). It states: ''This subchapter applies to rotorcraft external load operations transporting hazardous material on board, attached to, or suspended from an aircraft.'' The use of the term

[34] 85 FR 83366 (Dec. 21, 2020).

''subchapter'' is incorrect and instead, it should state ''section.'' PHMSA is replacing the term ''subchapter'' with the term ''section'' as appropriate.

Furthermore, paragraph (b) provides exceptions from HMR oversight. In final rule HM–218H,[35] PHMSA amended the HMR to make miscellaneous amendments to update and clarify certain regulatory requirements. One of the amendments made in § 175.9 was the removal of paragraph (b)(4), which excepted hazardous materials carried and used during dedicated air ambulance, firefighting, or search and rescue operations from being subject to the HMR when in compliance with applicable Federal Aviation Regulations (14 CFR) and any additional FAA requirements. At that time, PHMSA inserted paragraph (d) into § 175.1 with language to clarify that these types of air operations would otherwise be subject to the requirements in the HMR. However, the above revision left in place made an additional reference to an exception for firefighting and prevention, among other activities, in § 175.9(b)(6). The inclusion of firefighting and prevention in this exception is redundant because this aircraft operation activity is already covered under § 175.1(d) as not being subject to the HMR. Therefore, PHMSA is revising paragraph (b)(6) by removing reference to firefighting and prevention.

H. Part 177

Section 177.817

This section provides the requirements for shipping papers for hazardous materials transported by highway. Section 177.817(d) states: ''This subpart does not apply to a material that is excepted from shipping paper requirements as specified in § 172.200 of this subchapter.'' The use of the term ''subpart'' is not the most appropriate reference, as this would imply a hazardous material, which is excepted from shipping papers, would not be subject to all of subpart A of part 177. The appropriate term is ''section'' because the section prescribes the requirements for shipping papers for highway transportation; therefore, PHMSA is revising § 177.817(d) to read as follows: ''This section does not apply to a material that is excepted from shipping paper requirements as specified in § 172.200 of this subchapter.'' This amendment will ensure proper shipping papers and hazard information available for only the limited exception outlined in the section, which will support safe transportation of such hazardous materials.

Section 177.842

This section provides the requirements for Class 7 (radioactive) material transported by highway. Section 177.842(b)(2) provides instruction for the placement of certain radioactive material packages in a transport vehicle, storage location or in any other place according to the table found in paragraph (b)(2). Paragraph (b)(2) provides further instruction on how to handle and stow groups of packages when more than one is present in a storage location.'' However, the term ''stowed'' as used in paragraph (b)(2) is typically associated with vessel transport and not highway transport. The term ''stowage'' is defined in § 171.8 and means placing hazardous materials aboard a vessel and therefore, may be a source of confusion in this paragraph. PHMSA believes ''stored'' is the more appropriate term to use in the context of groups of packages present in one storage location. Therefore, PHMSA is revising the second sentence of § 177.842(b)(2) to the following: ''Each group of packages must be handled and stored together no closer than 6 m (20 feet) (measured edge to edge) to any other group. The following table is to be used in accordance with the provisions of paragraph (b) of this section:'' This amendment will alleviate any confusion on the method of transportation referenced and ensure safe transport of such radioactive material.

Section 177.848

This section provides the requirements for segregation of hazardous materials transported by highway. Specifically, § 177.848(e)(6) provides instruction for segregation of packages that display a subsidiary hazard label and uses the term ''stowed'' in the context of hazardous materials of the same class. However, the term ''stowed'' is typically associate with vessel transportation. Section 171.8 defines the term ''stowage'' as placing hazardous materials aboard a vessel. Furthermore, throughout every paragraph within § 177.848, the language ''loaded, transported, or stored together'' is used. Therefore, consistent with this language, PHMSA believes use of the term ''stored'' in § 177.848(e)(6) is more appropriate than ''stowed'' and is revising the second sentence of § 177.848(e)(6) accordingly. This amendment will alleviate any confusion regarding the method of transport applicable to this section.

I. Part 178

Section 178.50

This section provides the requirements for specification 4B welded or brazed steel cylinders. In final rule HM–220B,[36] RSPA amended the HMR by restructuring the cylinder specification requirements. The goal of the restructuring was to eliminate unnecessary pages within the HMR without substantially changing the regulatory requirements or affecting safety. Furthermore, the restructuring focused on these specific goals: (1) consolidating similar sections, (2) reformatting subpart C of part 178, and (3) revising section references throughout the HMR to correspond to revised sections. However, when RSPA restructured part 178, the language in § 178.50(a) was inadvertently changed and in doing so, gave the appearance that all specification 4B cylinders must have a longitudinal seam whereas the language in § 178.50(a) prior to HM–220B provided for specifications when cylinders have longitudinal seams. In addition, PHMSA issued a letter of interpretation [37] explaining this error and that PHMSA would correct the error in a future rulemaking. Therefore, PHMSA is revising the language from § 178.50(a) to be consistent with manufacturing of these cylinders where not all are made with longitudinal seams.

Section 178.337–1

This section provides the general requirements for specification MC 331 cargo tank motor vehicles. There is a typographical error in § 178.337–1(f) in the last sentence of the paragraph. It states: ''The post weld heat treatment must be as prescribed in Section VIII of the ASME Code, but in no event at less than 1,050 § F cargo tank metal temperature.'' The section symbol ''§ '' should instead read as the degree sign ''°.'' Therefore, PHMSA is revising this last sentence of paragraph (f) to include the temperature with the degree sign—1,050 °F.

Section 178.338–10

This section provides the accident damage protection requirements for specification MC–338 cargo tank motor vehicles. There is a typographical error in § 178.338–10(c)(2) where it states: ''Conform to the requirements of § 178.345–8(b).'' This is incorrect as § 178.345–8(b) is related to outlets for specification DOT 406, DOT 407, and DOT 412 cargo tank motor vehicles and

[35] 81 FR 35484 Jun. 2, 2016).

[36] 61 FR 25940 (May 23, 1996).

[37] Letter of Interpretation (Ref No. 15–0062).

not accident damage protection for specification MC–338 cargo tank motor vehicles. To clarify the correct citation, PHMSA is removing the reference to paragraph (b) and changing it to paragraph (d).

Section 178.601

This section provides the general requirements for specification packagings. The last sentence of § 178.601(g)(2)(vi) states, ''For packagings containing liquids, the absorbent material required in paragraph (g)(2)(v) of this section must be placed inside the means of containing liquid contents.'' The word ''as'' is missing before the second use of the word ''the'' that would give clearer context of the requirement that absorbent material required for packagings containing liquids must be placed inside as the means of containing the liquid contents rather than placing it inside the means of containing the liquid. Therefore, PHMSA is adding ''as'' to the sentence to read, ''For packagings containing liquids, the absorbent material required in paragraph (g)(2)(v) of this section must be placed inside as the means of containing liquid contents.''

J. Part 180

Section 180.507

This section provides the requirements for the qualification of tank cars. With regard to § 180.507(b), the title of paragraph (b), ''Tank car specifications no longer authorized for construction'' is misleading and a source of confusion as the title would imply that all specifications that follow in the paragraph are no longer authorized for construction, which is not the case. Rather, what follows is a table of tank car specifications that are no longer authorized for construction but allowed to remain in hazardous materials service if the tank cars adhere to the requirements of the HMR. Therefore, PHMSA is amending § 180.507(b)(1) to clarify that the tank specifications are no longer authorized, but tank cars built to the specifications may remain in hazardous materials service as long the requirements of the HMR are met. Additionally, PHMSA is amending the table in § 180.507(b)(1) to remove the very old ICC–105, 105A300, 105A400, 105A500, 105A600, ICC–27, BE–27, 106A500, and 106A800 specifications. These outmoded tanks were last authorized for construction over 50 years ago and are no longer in use in North America. Therefore, for clarity, we are removing these specifications from the table, as they would no longer be authorized for service. Similarly, we are removing Note 2, as no DOT–107A seamless steel tanks constructed between January 1, 1941, and December 31, 1955, are in service today.

Section 180.605

This section provides the requirements for periodic testing, inspection, and repair of portable tanks. Section 180.605(b)(5) provides one of five specified conditions that would require testing and inspection of a portable tank and states, ''The portable tank is in an unsafe operating condition based on the existence of probable cause.'' The terminology ''probable cause'' is typically reserved for criminal law and is inappropriate within the scope of conditions necessitating testing and inspection of a portable tank. Rather, the focus should be on the determination of unsafe operating conditions. Therefore, PHMSA is amending § 180.605(b)(5) by revising this paragraph to read, ''The portable tank is in an unsafe operating condition.''

V. Regulatory Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This final rule is published under the authority of the Federal Hazardous Materials Transportation Act (HMTA; 49 U.S.C. 5101–5127). Section 5103(b) of the HMTA authorizes the Secretary of Transportation to ''prescribe regulations for the safe transportation, including security, of hazardous materials in intrastate, interstate, and foreign commerce.'' The Secretary has delegated the authority granted in the HMTA to the PHMSA Administrator at 49 CFR 1.97(b).

PHMSA finds it has good cause to make these changes without notice and comment pursuant to Section 553(b) of the Administrative Procedure Act (APA, 5 U.S.C., 551, *et seq.*). Section 553(b)(B) of the APA provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. As explained above, the editorial and ministerial amendments to these regulations make no substantive changes to the regulations, but merely facilitate further compliance with the existing regulations by correcting information (*e.g.,* mailing addresses) and otherwise providing increased clarity for certain provisions.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866 (''Regulatory Planning and Review'') [38] requires agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' Similarly, DOT regulations require that regulations issued by PHMSA and other DOT Operating Administrations ''should be designed to minimize burdens and reduce barriers to market entry whenever possible, consistent with the effective promotion of safety'' and should generally ''not be issued unless their benefits are expected to exceed their costs.'' This final rule does not impose new burdens as the amendments contained in this final rule are non-substantive changes that do not impose new requirements for hazardous materials shippers or carriers. Therefore, it is not necessary to prepare a regulatory impact analysis.

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was not reviewed by the Office of Management and Budget. Nor is this final rule considered a significant rulemaking under the DOT rulemaking procedures at 49 CFR part 5.

C. Executive Order 13132

This final rule has been analyzed in accordance with the principles and criteria in Executive Order 13132 (''Federalism'') [39] and its implementing Presidential Memorandum (''Preemption'').[40] Executive Order 13132 requires agencies to assure meaningful and timely input by state and local officials in the development of regulatory policies that may 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.''

The HMR amendments in this final rule are non-substantive changes that do not impose any new requirements and will not have substantial direct effects 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. Nor do the HMR amendments in this final rule impose direct compliance costs on state and local governments. Therefore, the

[38] 58 FR 51735, (Oct. 4, 1993).

[39] 64 FR 43255 (Aug. 10, 1999).

[40] 74 FR 24693 (May 22. 2009).

consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13175

PHMSA analyzed this final rule in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments'') [41] and DOT Order 5301.1, ''Department of Transportation Policies, Programs, and Procedures Affecting American Indians, Alaska Natives, and Tribes.''

Executive Order 13175 and DOT Order 5301.1 require DOT Operating Administrations to assure meaningful and timely input from Indian Tribal government representatives in the development of rules that significantly or uniquely affect tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship and distribution of power between the Federal Government and Native American Tribes.

PHMSA assessed the impact of this final rule and determined that it does not significantly or uniquely affect tribal communities or Native American Tribal governments. The changes to the HMR as written in this final rule are facially neutral and have broad, national scope; PHMSA therefore expects this final rule not to affect tribal communities significantly or uniquely, much less impose substantial compliance costs on Native American Tribal governments or mandate tribal action. Because PHMSA expects this final rule will not adversely affect the safe transportation of hazardous materials generally, PHMSA does not expect it will entail disproportionately high adverse risks for tribal communities. For these reasons, PHMSA finds the funding and consultation requirements of Executive Order 13175 and DOT Order 5301.1 do not apply.

E. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to review regulations to assess their impact on small entities unless the agency head certifies that a rulemaking will not have a significant economic impact on a substantial number of small entities, including small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where possible to do so and still meet the objectives of applicable regulatory statutes. Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') [42] requires agencies to establish procedures and policies to promote compliance with the Regulatory Flexibility Act and to ''thoroughly review draft rules to assess and take appropriate account of the potential impact'' of the rules on small businesses, governmental jurisdictions, and small organizations. The DOT posts its implementing guidance on a dedicated web page.[43]

This final rule has been developed in accordance with Executive Order 13272 and with DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of draft rules on small entities are properly considered. There are no costs to small entities associated with this final rule. This final rule makes non-substantive changes that do not impose new requirements; thus, there are no direct or indirect adverse economic impacts for small units of government, businesses, or other organizations. Consequently, PHMSA certifies that this final rule does not have a significant economic impact on a substantial number of small entities.

F. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) requires agencies to assess the effects of Federal regulatory actions on state, local, and tribal governments, and the private sector. For any NPRM or final rule that includes a federal mandate that may result in the expenditure by state, local, and tribal governments, or by the private sector of $100 million or more in 1996 dollars in any given year, the agency must prepare, amongst other things, a written statement that qualitatively and quantitatively assesses the costs and benefits of the Federal mandate.

This final rule does not impose unfunded mandates under the UMRA. It does not result in costs of $100 million or more in 1996 dollars to either state, local, or tribal governments, or to the private sector in any one year and is the least burdensome alternative that achieves the objective of the rule.

G. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), no person is required to respond to any information collection unless it has been approved by OMB and displays a valid OMB control number. Section 1320.8(d) of 5 CFR requires that PHMSA provide interested members of the public and affected agencies an opportunity to comment on information and recordkeeping requests. There are no new or modified information collection requirements in this final rule.

H. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and implementing regulations by the Council on Environmental Quality (40 CFR part 1500) requires federal agencies to consider the consequences of federal actions and prepare a detailed statement on actions that significantly affect the quality of the human environment. DOT Order 5610.1C, ''Procedures for Considering Environmental Impacts,'' establishes departmental procedures for evaluating environmental impacts under NEPA and its implementing regulations. The purpose of this final rule is to introduce non-substantive changes that do not impose new requirements. The intended effect of this rule is to enhance the accuracy and reduce misunderstandings of the regulations. Therefore, PHMSA has determined that implementing this final rule will not significantly impact the quality of the human environment.

I. Environmental Justice

Executive Orders 12898 (''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations''),[44] 13985 (''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government''),[45] 13990 (''Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis''),[46] 14008 (''Tackling the Climate Crisis at Home and Abroad''),[47] and DOT Order 5610.2C (''Department of Transportation Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'') require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high

[41] 65 FR 67249 (Nov. 9, 2000).

[42] 68 FR 7990 (Feb. 19, 2003).

[43] DOT, ''Rulemaking Requirements Related to Small Entities,'' *https://www.transportation.gov/regulations/rulemaking-requirements-concerning-small-entities* (last accessed June 17, 2021).

[44] 59 FR 7629 (Feb. 16, 1994).

[45] 86 FR 7009 (Jan. 20, 2021).

[46] 86 FR 7037 (Jan. 20, 2021).

[47] 86 FR 7619 (Feb. 1, 2021).

and adverse human health or environmental effects, including interrelated social and economic effects of their programs, policies, and activities on minority populations, low-income populations, and other underserved and disadvantaged communities.

PHMSA has evaluated this final rule under the above Executive Orders and DOT Order 5610.2C and does not expect the final rule to cause disproportionately high and adverse human health and environmental effects on minority, low-income, underserved, and other disadvantaged populations and communities. The rulemaking is facially neutral and national in scope; it is neither directed toward a particular population, region, or community, nor is it expected to impact any particular population, region, or community adversely. Because PHMSA does not expect this final rulemaking to adversely affect the safe transportation of hazardous materials generally, and because the amendments in this final rule are non-substantive changes, PHMSA does not expect the proposed revisions would entail disproportionately high adverse risks for minority populations, low-income populations, or other underserved and other disadvantaged communities.

J. Executive Order 13609 and International Trade Analysis

Under Executive Order 13609 (''Promoting International Regulatory Cooperation''),[48] agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465) (as amended, the Trade Agreements Act), prohibits federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to the Trade Agreements Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in establishing international standards to protect the safety of the American public. PHMSA has assessed the effects of the final rule to ensure that it does not cause unnecessary obstacles to foreign trade. The amendments contained in this rule are non-substantive changes and do not impose new requirements. Further, insofar as many of the amendments introduced by the final rule improve the clarity of the HMR for regulated entities or better align the HMR with international (*e.g.,* IAEA) standards, the final rule could reduce barriers to international trade. Therefore, this final rule does not present an obstacle to international trade, and accordingly, this final rule is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreements Act.

List of Subjects

49 CFR Part 107

Hazardous Materials Program Procedures

49 CFR Part 110

Hazardous Materials Public Sector Training and Planning Grants

49 CFR Part 171

General Information, Regulations, and Definitions

49 CFR Part 172

Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans

49 CFR Part 173

Shippers—General Requirements for Shipments and Packagings

49 CFR Part 174

Carriage by Rail

49 CFR Part 175

Carriage by Aircraft

49 CFR Part 176

Carriage by Vessel

49 CFR Part 177

Carriage by Public Highway

49 CFR Part 178

Specifications for Packagings

49 CFR Part 180

Continuing Qualification and Maintenance of Packagings.

In consideration of the foregoing, 49 CFR chapter I is amended as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM AND PROCEDURES

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 Section 4; Pub. L. 104–121 Sections 212–213; Pub. L. 104–134 Section 31001; Pub. L. 114–74 Section 4 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

■ 2. In § 107.109, revise paragraph (a)(4) to read as follows:

§ 107.109 Application for renewal.

* * * * *

(a) * * *

(4) The application must include either a certification by the applicant that the original application, as it may have been updated by any application for renewal, remains accurate (*e.g.,* all section references, shipping descriptions, email address, etc.) and complete; or include an amendment to the previously submitted application as is necessary to update and ensure the accuracy and completeness of the application, with certification by the applicant that the application as amended is accurate and complete.

* * * * *

■ 3. In Appendix A to subpart D of part 107, in section II, under the heading ''Offeror Requirements—All hazardous materials'':

■ a. Remove the entry A.1.d., ''Consumer Commodity, ORM–D'';

■ b. Revise the entry ''A.2'' violation description; and

■ c. Revise the entry ''G.1'' violation description.

The revisions read as follows:

Appendix A to Subpart D of Part 107—Guidelines for Civil Penalties

* * * * *

[48] 77 FR 26413 (May 4, 2012).

Violation description	Section or cite	Baseline assessment
* * * * * * *		
Offeror Requirements—All hazardous materials		
* * * * * * *		
A. * * * 2. Offering for transportation a hazardous material that is misclassified on the shipping paper, markings, labels, and placards:.		
* * * * * * *		
G. * * * 1. Failure to comply with package testing requirements for small quantities, excepted quantities, de minimis, materials of trade, and limited quantities.	173.4, 173.4a, 173.4b, 173.6, 173.156, 173.306.	$1,000 to $5,000.
* * * * * * *		

* * * * *

■ 4. In § 107.502, revise paragraph (d) to read as follows:

§ 107.502 General registration requirements.

* * * * *

(d) Registration statements must be in English, contain all the information required by this subpart, and be submitted to: FMCSA Hazardous Materials Division—MC–SEH, West Building, 1200 New Jersey Avenue SE, Washington, DC 20590.

* * * * *

PART 110—HAZARDOUS MATERIALS PUBLIC SECTOR TRAINING AND PLANNING GRANTS

■ 5. The authority citation for part 110 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.97.

■ 6. Revise § 110.7 to read as follows:

§ 110.7 Control number under the Paperwork Reduction Act.

The Office of Management and Budget control number assigned for the collection of information in § 110.30 is 2137–0586.

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 7. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410 section 4; Pub. L. 104–134, section 31001; Pub. L. 114–74 section 4 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 8. In § 171.6, revise paragraph (b)(2) introductory text and add an entry for ''2137–0628'' in numerical order to the table to read as follows:

§ 171.6 Control numbers under the Paperwork Reduction Act.

* * * * *

(b) * * *

(2) Table 1 to paragraph (b)(2):

Current OMB control No.	Title	Title 49 CFR part or section where identified and described
* * * * * * *		
2137–0628	Flammable Hazardous Materials by Rail Transportation	§§ 130.120, 171.16, 173.41, 173.145, 173.150, 174.310, 174.312.

■ 9. In § 171.7, revise paragraphs (b)(1), (n) introductory text, and (w)(22) to read as follows:

§ 171.7 Reference material.

* * * * *

(b) * * *

(1) ATA Specification No. 300 Packaging of Airline Supplies, Revision 19, July 31, 1996, into §§ 172.102, 173.168, 173.302, and 173.304.

* * * * *

(n) *Compressed Gas Association (CGA),* 8484 Westpark Drive, Suite 220, McLean, VA 22102.

* * * * *

(w) * * *

(22) ISO 4706:2008(E), Gas cylinders—Refillable welded steel cylinders—Test pressure 60 bar and below, First Edition, 2008–04–15, Corrected Version, 2008–07–01, into § 178.71.

* * * * *

■ 10. In § 171.8:

■ a. Revise the definition of ''Agricultural product''; and<

■ b. Remove the first definition of ''Oxidizing gas''.

The revision reads as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

Agricultural product means a hazardous material, other than a hazardous waste, whose end use directly supports the production of an agricultural commodity including, but not limited to a fertilizer, pesticide, soil amendment or fuel. An *agricultural product* is limited to a material in Class 3, 8 or 9, Division 2.1, 2.2, 5.1, or 6.1.

* * * * *

■ 11. In § 171.12, revise paragraph (b)(4) to read as follows:

§ 171.12 North American Shipments.

* * * * *

(b) * * *

(4) Except as provided in paragraph (b)(5) of this section, the package must be labeled or placarded POISON GAS or POISON INHALATION HAZARD, as appropriate, in accordance with subparts E and F to part 172 of this subchapter.

* * * * *

■ 12. In § 171.15, revise paragraph (a) introductory text to read as follows:

§ 171.15 Immediate notice of certain hazardous materials incidents.

(a) *General.* As soon as practical but no later than 12 hours after the occurrence of any incident described in paragraph (b) of this section, each person in physical possession of the hazardous material must provide notice by telephone to the National Response Center (NRC) on 800–424–8802 (toll free) or 202–267–2675 (toll call). Each notice must include the following information:

* * * * *

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGERNCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 13. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 14. In § 172.101:

■ a. Revise paragraphs (f) and (i)(3); and

■ b. Amend the Hazardous Materials Table by removing the entries under ''[REMOVE],'' revising the entries under ''[REVISE]'', and adding in the appropriate alphabetical order the entries under ''[ADD].''

The revisions and additions read as follows:

§ 172.101 Purpose and use of hazardous materials table.

* * * * *

(f) *Column 5: Packing group.* Column 5 specifies one or more packing groups assigned to a material corresponding to the proper shipping name and hazard class for that material. Class 2, Class 7, and Division 6.2 do not have packing groups. Articles in classes other than Class 1 are not assigned to packing groups. For packing purposes, any requirement for a specific packaging performance level is set out in the applicable packing authorizations of part 173. Packing Groups I, II, and III indicate the degree of danger presented by the material is great, medium, or minor, respectively. If more than one packing group is indicated for an entry, the packing group for the hazardous material is determined using the criteria for assignment of packing groups specified in subpart D of part 173. When a reevaluation of test data or new data indicates a need to modify the specified packing group(s), the data should be submitted to the Associate Administrator. Each reference in this column to a material that is a hazardous waste or a hazardous substance, and whose proper shipping name preceded in Column 1 of the Table by the letter ''A'' or ''W,'' is modified to read ''III'' on those occasions when the material is offered for transportation or transported by a mode in which its transportation is not otherwise subject to requirements of this subchapter.

* * * * *

(i) * * *

(3) *Bulk packaging.* Column (8C) specifies the section in part 173 of this subchapter that prescribes packaging requirements for bulk packagings, subject to the limitations, requirements, and additional authorizations of Columns (7) and (8B). A ''None'' in Column (8C) means bulk packagings are not authorized, except as may be provided by special provisions in Column (7) and in packaging authorizations Column (8B). Additional authorizations and limitations for use of UN portable tanks are set forth in Column 7. For each reference in this column to a material that is a hazardous waste or a hazardous substance, and whose proper shipping name is preceded in Column 1 of the Table by the letter ''A'' or ''W'' and that is offered for transportation or transported by a mode in which its transportation is not otherwise subject to the requirements of this subchapter:

(i) The column reference is § 173.240 or § 173.241, as appropriate.

(ii) For a solid material, the exception provided in special provision B54 is applicable.

(iii) For a Class 9 material, which meets the definition of an elevated temperature material, the column reference is § 173.247.

* * * * *

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification numbers	PG	Label codes	Special provisions (§ 172.102)	(8) Packaging (§ 173.***)		(9) Quantity limitations (see §§ 173.27 and 175.75)			(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	[REMOVE].												
	*	*			*	*	*		*	*			
G	Amine, liquid, corrosive, flammable, n.o.s. or Polyamines, liquid, corrosive, flammable, n.o.s..	8	UN2734	I	8, 3 ..	A3, A6, N34, T14, TP2, TP27.	None	201	243	0.5 L	2.5 L	A	52
				II	8, 3 ..	IB2, T11, TP2, TP27	154	201	243	1 L	30 L	A	52
	*	*			*	*	*		*	*			
D	Cartridges power device *(used to project fastening devices).*	ORM–D	.....	.....	None	222	63	None	None	30 kg gross	Forbidden ...	A	.....
	*	*			*	*	*		*	*			
D	Cartridges, small arms	ORM–D	.....	.....	None	222	63	None	None	30 kg gross	Forbidden ...	A	.....
	*	*			*	*	*		*	*			
D	Consumer commodity	ORM–D	.....	.....	None	22	156, 306	156, 306	None	30 kg gross	Forbidden ...	A	.....
	*	*			*	*	*		*	*			
	Hydrogen, peroxide, aqueous solutions with more than 40 percent but not more than 60 percent hydrogen peroxide (stabilized as necessary).	5.1	UN2014	II	5.1, 8	12, A60, B53, B80, B81, B85, IB2, IP5, T7, TP2, TP6, TP24, TP37.	152	202	243	Forbidden ...	Forbidden ...	D	25, 66, 75
	Hydrogen peroxide, aqueous solutions with not less than 20 percent but not more than 40 percent hydrogen peroxide (stabilized as necessary).	5.1	UN2014	II	5.1, 8	A2, A3, A6, B53, IB2, IP5, T7, TP2, TP6, TP24, TP37.	152	202	243	1 L	5 L	D	25, 66, 75
	*	*			*	*	*		*	*			
	Paint *including paint, lacquer, enamel, stain, shellac solutions, varnish, polish, liquid filler and liquid lacquer base.*	3	UN1263	I	3	367, T11, TP1, TP8, TP27.	150	201	243	1 L	30 L	E	.....
				II	3	149, 367, B52, B131, IB2, T4, TP1, TP8, TP28.	150	173	242	5 L	60 L	B	.....
				III	3	367, B1, B52, B131, IB3, T2, TP1, TP29.	150	173	242	60 L	220 L	A	.....
	*	*			*	*	*		*	*			
	Wheel chair, electric, see Battery powered vehicle *or* Battery powered equipment.												
	*	*			*	*	*		*	*			
	[REVISE].												
	*	*			*	*	*		*	*			
	Amyl mercaptan	3	UN1111	II	3	A3, IB2, T4, TP1	150	202	242	5 L	60 L	B	95, 102

§ 172.101 HAZARDOUS MATERIALS TABLE—Continued

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification numbers	PG	Label codes	Special provisions (§ 172.102)	(8) Packaging (§ 173.***)		(9) Quantity limitations (see §§ 173.27 and 175.75)			(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	*	*	*		*	*	*		*	*			
	Antimony pentafluoride	8	UN1732	II	8, 6.1	A3, A7, A10, IB2, N3, N36, T7, TP2.	154	202	243	Forbidden	30 L	D	40, 44, 53, 58, 89, 100, 141
	*	*	*		*	*	*		*	*			
	Coating solution *(includes surface treatments or coatings used for industrial or other purposes such as vehicle undercoating, drum or barrel lining).*	3	UN1139	I	3	T11, TP1, TP8, TP27.	150	201	243	1 L	30 L	E	
				II	3	149, 383, IB2, T4, TP1, TP8.	150	202	242	5 L	60 L	B	
				III	3	B1, IB3, T2, TP1	150	203	242	60 L	220 L	A	
	*	*	*		*	*	*		*	*			
G	Corrosive liquids, flammable, n.o.s.	8	UN2920	I	8, 3	B10, T14, TP2, TP27.	None	201	243	0.5 L	2.5 L	C	25, 40
				II	8, 3	B2, IB2, T11, TP2, TP27.	154	202	243	1 L	30 L	C	25, 40
	*	*	*		*	*	*		*	*			
G	Corrosive solids, flammable, n.o.s.	8	UN2921	I	8, 4.1	IB6, T6, TP33	None	211	242	1 kg	25 kg	B	12, 25
				II	8, 4.1	IB8, IP2, IP4, T3, TP33.	154	212	242	15 kg	50 kg	B	12, 25
	*	*	*		*	*	*		*	*			
G	Corrosive liquids, oxidizing, n.o.s.	8	UN3093	I	8, 5.1	A7	None	201	243	Forbidden	2.5 L	C	89
				II	8, 5.1	A7, IB2	154	202	243	1 L	30 L	C	89
	*	*	*		*	*	*		*	*			
G	Corrosive solids, oxidizing, n.o.s.	8	UN3084	I	8, 5.1	T6, TP33	None	211	242	1 kg	25 kg	C	
				II	8, 5.1	IB6, IP2, T3, TP33	154	212	242	15 kg	50 kg	C	
	*	*	*		*	*	*		*	*			
	Dangerous goods in articles *or* Dangerous goods in machinery *or* Dangerous goods in apparatus.	9	UN3363		9	136, A105	None	222	None	*See* A105	*See* A105	A	
	*	*	*		*	*	*		*	*			
	Difluorophosphoric acid, anhydrous	8	UN1768	II	8	A7, B2, IB2, N5, N34, T8, TP2.	154	202	242	1 L	30 L	A	40, 53, 58
	*	*	*		*	*	*		*	*			
	Diethyl sulfide	3	UN2375	II	3	IB2, T7, TP1, TP13	150	202	243	5 L	60 L	E	
	*	*	*		*	*	*		*	*			
A, W	Fish meal, stabilized *or* Fish scrap, stabilized.	9	UN2216	III	None	155, B136, IB8, IP3, T1, TP33.	155	218	218	100 kg	200 kg	B	25, 88, 122, 128
	*	*	*		*	*	*		*	*			
G	Flammable solids, corrosive, organic, n.o.s..	4.1	UN2925	II	4.1, 8	A1, IB6, IP2, T3, TP33.	151	212	242	15 kg	50 kg	D	40
				III	4.1, 8	A1, IB6, T1, TP33	151	213	242	25 kg	100 kg	D	40

	*		*		*	*	*	*	*	*				
	Fluorophosphoric acid anhydrous	8	UN1776	II	8	A7, B2, IB2, N3, N34, T8, TP2.	154	202	242	1 L	30 L	A	53, 58
	*		*		*	*	*	*	*	*				
	Fluorosilicic acid	8	UN1778	II	8	A7, B2, B15, IB2, N3, N34, T8, TP2.	154	202	242	1 L	30 L	A	53, 58
	*		*		*	*	*	*	*	*				
	Hexafluorophosphoric acid	8	UN1782	II	8	A7, B2, IB2, N3, N34, T8, TP2.	154	202	242	1 L	30 L	A	53, 58
	*		*		*	*	*	*	*	*				
	Hexamethylenediamine solution	8	UN1783	II	8	52, IB2, T7, TP2	154	202	242	1 L	30 L	A	52
	*		*		*	*	*	*	*	*				
	Hydrobromic acid, *with more than 49 percent hydrobromic acid.*	8	UN1788	II	8	A3, B2, B15, IB2, N41, T7, TP2.	154	202	242	1 L	30 L	C	53, 58
				III	8	A3, IB3, T4, TP1	154	203	241	5 L	60 L	C	53, 58
	*		*		*	*	*	*	*	*				
	Hydrogendifluoride, solid, n.o.s.	8	UN1740	II	8	IB8, IP2, IP4, N3, N34, T3, TP33.	154	212	240	15 kg	50 kg	A	25, 40, 52, 53, 58
				III	8	53, 58, IB8, IP3, N3, N34, T1, TP33.	154	213	240	25 kg	100 kg	A	25, 40, 52
	*		*		*	*	*	*	*	*				
	Hydrogen peroxide and peroxyacetic acid mixtures, stabilized *with acids, water, and not more than 5 percent peroxyacetic acid.*	5.1	UN3149	II	5.1, 8	145, A2, A3, B53, IB2, IP5, T7, TP2, TP6, TP24.	152	202	243	1 L	5 L	D	25, 66, 75
	*		*		*	*	*	*	*	*				
	Mercaptans, liquid, flammable, toxic, n.o.s. *or* Mercaptan mixtures, liquid, flammable, toxic, n.o.s..	3	UN1228	II	3, 6.1	IB2, T11, TP2, TP27	150	202	243	Forbidden	60 L	B	40, 95, 102
				III	3, 6.1	B1, IB3, T7, TP1, TP28.	150	203	242	5 L	220 L	A	40, 95, 102
	*		*		*	*	*	*	*	*				
	Nitric acid *other than red fuming, with at least 65 percent, but not more than 70 percent nitric acid.*	8	UN2031	II	8, 5.1	B2, B47, B53, IB2, IP15, T8, TP2.	154	158	242	Forbidden	30 L	D	53, 58, 66, 74, 89, 90
	Nitric acid *other than red fuming, with more than 20 percent and less than 65 percent nitric acid.*	8	UN2031	II	8	A212, B2, B47, B53, IB2, IP15, T8, TP2.	154	158	242	Forbidden	30 L	D	44, 66, 53, 58, 74, 89, 90
	Nitric acid *other than red fuming with not more than 20 percent nitric acid.*	8	UN2031	II	8	B2, B47, B53, IB2, T8, TP2.	154	158	242	1 L	30 L	D	53, 58
	*		*		*	*	*	*	*	*				
G	Nitrites, inorganic, n.o.s.	5.1	UN2627	II	5.1	33, IB8, IP2, IP4, T3, TP33.	152	212	None	5 kg	25 kg	A	46, 56, 58, 133
	*		*		*	*	*	*	*	*				
G	Oxidizing liquid, corrosive, n.o.s.	5.1	UN3098	I	5.1, 8	62	None	201	244	Forbidden	2.5 L	D	13, 56, 58, 138
				II	5.1, 8	62, IB1	152	202	243	1 L	5 L	B	13, 56, 58, 138
				III	5.1, 8	62, IB2	152	203	242	2.5 L	30 L	B	13, 56, 58, 138

§ 172.101 HAZARDOUS MATERIALS TABLE—Continued

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification numbers	PG	Label codes	Special provisions (§ 172.102)	(8) Packaging (§ 173.***)		(9) Quantity limitations (see §§ 173.27 and 175.75)			(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	*	*	*		*	*	*		*	*			
G	Pesticides, liquid, flammable, toxic, *flash point less than 23 degrees C.*	3	UN3021	I	3, 6.1	B5, T14, TP2, TP13, TP27.	None	201	243	Forbidden	30 L	B	40
	*	*	*		*	*	*		*	*			
	Phosphorus tribromide	8	UN1808	II	8	A3, A7, B2, B25, IB2, N34, N43, T7, TP2.	154	202	242	Forbidden	30 L	C	40, 53, 58
	*	*	*		*	*	*		*	*			
	1,2-Propylenediamine	8	UN2258	II	8	A3, IB2, N34, T7, TP2.	154	202	243	1 L	30 L	A	40, 52
	*	*	*		*	*	*		*	*			
	Radioactive material, low specific activity (LSA–II) *non fissile or fissile-excepted.*	7	UN3321		7	325, A56, T5, TP4, W7.	421, 422, 428.	427	427			A	95, 129
	*	*	*		*	*	*		*	*			
+	Tetranitromethane	6.1	UN1510	I	6.1, 5.1.	2, B32, T20, TP2, TP13, TP38, TP44.	None	227	None	Forbidden	Forbidden	D	40, 66
	*	*	*		*	*	*		*	*			
	[ADD].												
	*	*	*		*	*	*		*	*			
G	Amine, liquid, corrosive, flammable, n.o.s. *or* Polyamines, liquid, corrosive, flammable, n.o.s..	8	UN2734	I	8, 3	A3, N34, T14, TP2, TP27.	None	201	243	0.5 L	2.5 L	A	52
				II	8, 3	IB2, T11, TP2, TP27	154	202	243	1 L	30 L	A	52
	*	*	*		*	*	*		*	*			
	Hydrogen peroxide, aqueous solutions *with more than 40 percent but not more than 60 percent hydrogen peroxide (stabilized as necessary).*	5.1	UN2014	II	5.1, 8	12, A60, B53, B80, B81, B85, IB2, IP5, T7, TP2, TP6, TP24, TP37.	152	202	243	Forbidden	Forbidden	D	25, 66, 75
	Hydrogen peroxide, aqueous solutions *with not less than 20 percent but not more than 40 percent hydrogen peroxide (stabilized as necessary).*	5.1	UN2014	II	5.1, 8	A2, A3, B53, IB2, IP5, T7, TP2, TP6, TP24, TP37.	152	202	243	1 L	5 L	D	25, 66, 75
	*	*	*		*	*	*		*	*			
	Paint *(including paint, lacquer, enamel, stain, shellac solutions, varnish, polish, liquid filler and liquid lacquer base).*	3	UN1263	I	3	367, T11, TP1, TP8, TP27.	150	201	243	1 L	30 L	E	
				II	3	149, 367, 383, B52, B131, IB2, T4, TP1, TP8, TP28.	150	173	242	5 L	60 L	B	

				III	3	367, B1, B52, B131, IB3, T2, TP1, TP29.	150	173	242	60 L	220 L	A	

* * * * * * *

	Wheelchair, electric, see Battery powered vehicle *or* Battery powered equipment.												

* * * * * * *

* * * * *

■ 15. In § 172.102:

■ a. Remove special provision ''222'' from the ''Code/Special Provisions'' table in paragraph (c)(1); and

■ b. Revise the entry for ''IP7'' in Table 2—IP Codes in paragraph (c)(4).

The revision reads as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(4) * * *

TABLE 2—IP CODES

IP code	
*	* * * * * * *
IP7	For UN identification numbers 1327, 1363, 1364, 1365, 1386, 1408, 1841, 2211, 2217, 2793 and 3314, IBCs are not required to meet the IBC performance tests specified in part 178, subpart N, of this subchapter.
*	* * * * * * *

* * * * *

■ 16. In § 172.200, revise paragraph (b)(3) to read as follows:

§ 172.200 Applicability.

* * * * *

(b) * * *

(3) A limited quantity package unless the material is offered for transportation by aircraft or vessel.

* * * * *

■ 17. In § 172.202, revise paragraph (a)(4) to read as follows:

§ 172.202 Description of hazardous material on shipping papers.

(a) * * *

(4) The packing group in Roman numerals, as designated for the hazardous material in Column (5) of the § 172.101 table. Class 1 (explosives) materials; self-reactive substances; Division 5.2 materials; and entries that are not assigned a packing group (*e.g.,* Class 7) are excepted from this requirement. The packing group may be preceded by the letters ''PG'' (for example, ''PG II''); and

* * * * *

■ 18. In § 172.203, revise paragraph (e)(2) to read as follows:

§ 172.203 Additional description requirements.

* * * * *

(e) * * *

(2) The description on the shipping paper for a tank car containing the residue of a hazardous material must include the phrase, ''RESIDUE: Last Contained * * *'' immediately before or after the basic shipping description or immediately preceding the proper shipping name of the material on the shipping paper.

* * * * *

■ 19. In § 172.204, revise paragraph (a)(3)(ii) to read as follows:

§ 172.204 Shipper's certification.

(a) * * *

(3) * * *

(ii) *Electronic certification.* When transmitted electronically, by completing the field designated for the shipper's signature with the name of the principal person, partner, officer, or employee of the offeror or their agent, the shipper is also certifying its compliance with the certification specified in this paragraph (a).

* * * * *

§ 172.315 [Amended]

■ 20. In § 172.315, remove and reserve paragraph (d).

§ 172.316 [Removed and Reserved]

■ 21. Remove and reserve § 172.316.

■ 22. In § 172.332, revise paragraph (d) to read as follows:

§ 172.332 Identification number markings.

* * * * *

(d) *Example.* Except for size and color, the display of an identification number on a placard shall be as illustrated for Acetone:

■ 23. In § 172.400, revise the table to paragraph (b) to read as follows:

§ 172.400 General labeling requirements.

(b) * * *

* * * * *

TABLE 1 TO PARAGRAPH (b)

Hazard class or division	Label name	Label design or section reference
1.1	EXPLOSIVES 1.1	172.411
1.2	EXPLOSIVES 1.2	172.411
1.3	EXPLOSIVES 1.3	172.411
1.4	EXPLOSIVES 1.4	172.411
1.5	EXPLOSIVES 1.5	172.411
1.6	EXPLOSIVES 1.6	172.411
2.1	FLAMMABLE GAS	172.417
2.2	NON–FLAMMABLE GAS	172.415
2.3	POISON GAS	172.416
3 Flammable Liquid (Combustible liquid)	FLAMMABLE LIQUID (none)	172.419
4.1	FLAMMABLE SOLID	172.420
4.2	SPONTANEOUSLY COMBUSTIBLE	172.422
4.3	DANGEROUS WHEN WET	172.423
5.1	OXIDIZER	172.426
5.2	ORGANIC PEROXIDE	172.427
6.1 (material poisonous by inhalation (see § 171.8 of this subchapter)).	POISON INHALATION HAZARD	172.429
6.1 (other than a material poisonous by inhalation)	POISON	172.430
6.1 (inhalation hazard, Zone A or B)	POISON INHALATION HAZARD	172.429
6.1 (other than inhalation hazard, Zone A or B)	POISON	172.430
6.2	INFECTIOUS SUBSTANCE	172.432
7 (see § 172.403)	RADIOACTIVE WHITE–I	172.436
7	RADIOACTIVE YELLOW–II	172.438
7	RADIOACTIVE YELLOW–III	172.440
7 (fissile radioactive material; see § 172.402)	FISSILE	172.441
7 (empty packages, see § 173.428 of this subchapter)	EMPTY	172.450
8	CORROSIVE	172.442
9	CLASS 9	172.446

§ 172.500 [Amended]

■ 24. In § 172.500, remove paragraph (b)(2) and redesignate paragraphs (b)(3) through (6) as paragraphs (b)(2) through (5) to read as follows:

■ 25. In § 172.504, in paragraph (e), designate table 1 as Table 1 to Paragraph (e) and revise table 2 to read as follows:

§ 172.504 General placarding requirements.

* * * * *

(e) * * *

TABLE 2 TO PARAGRAPH (e)

Category of material (hazard class or division number and additional description, as appropriate)	Placard name	Placard design section reference (§)
1.4	EXPLOSIVES 1.4	172.523
1.5	EXPLOSIVES 1.5	172.524
1.6	EXPLOSIVES 1.6	172.525
2.1	FLAMMABLE GAS	172.532
2.2	NON–FLAMMABLE GAS	172.528
3	FLAMMABLE	172.542
Combustible liquid	COMBUSTIBLE	172.544
4.1	FLAMMABLE SOLID	172.546
4.2	SPONTANEOUSLY COMBUSTIBLE	172.547
5.1	OXIDIZER	172.550
5.2 (Other than organic peroxide, Type B, liquid or solid, temperature controlled).	ORGANIC PEROXIDE	172.552
6.1 (other than material poisonous by inhalation)	POISON	172.554
6.2	NONE	
8	CORROSIVE	172.558
9	CLASS 9 (see § 172.504(f)(9))	172.560

* * * * *

■ 26. In § 172.512, revise paragraph (c) to read as follows:

§ 172.512 Freight containers and aircraft unit load devices.

* * * * *

(c) Notwithstanding paragraphs (a) and (b) of this section, packages containing hazardous materials offered for transportation by air in freight containers are subject to the inspection requirements of § 175.30 of this chapter.

■ 27. In § 172.519, revise paragraph (c)(1) to read as follows:

* * * * *

(c) * * *

(1) Each diamond (square-on-point) placard prescribed in this subpart must measure at least 250 mm (9.84 inches) on each side and must have a solid line inner border approximately 12.5 mm inside and parallel to the edge. The 12.5 mm measurement is from the outside edge of the placard to the outside of the solid line forming the inner border. For domestic transportation, a placard manufactured prior to January 1, 2017, in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue in service until the end of its useful life provided the color tolerances are maintained and are in accordance with the display requirements of this subchapter.

* * * * *

■ 28. In § 172.600, revise paragraph (d) to read as follows:

§ 172.600 Applicability and general requirements.

* * * * *

(d) *Exceptions.* The requirements of this subpart do not apply to hazardous material which is excepted from the shipping paper requirements of this subchapter.

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 29. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 30. Section 173.2 is revised to read as follows:

§ 173.2 Hazardous material classes and index to hazard class definitions.

The hazard class of a hazardous material is indicated by either the class or division number or the class name. The following table lists class numbers, division numbers, class or division names and those sections of this subchapter which contain definitions for classifying hazardous materials, including forbidden materials.

TABLE 1 TO § 173.2

Class No.	Division number (if applicable)	Name of class or division	49 CFR reference for definitions
None		FORBIDDEN MATERIALS	173.21
None		FORBIDDEN EXPLOSIVES	173.54
1	1.1	EXPLOSIVES (WITH A MASS EXPLOSION HAZARD)	173.50
1	1.2	EXPLOSIVES (WITH A PROJECTION HAZARD)	173.50
1	1.3	EXPLOSIVES (WITH PREDOMINATELY A FIRE HAZARD)	173.50
1	1.4	EXPLOSIVES (WITH NO SIGNIFICANT BLAST HAZARD)	173.50
1	1.5	VERY INSENSITIVE EXPLOSIVES; BLASTING AGENTS	173.50
1	1.6	EXTREMELY INSENSITIVE DETONATING SUBSTANCES	173.50
2	2.1	FLAMMABLE GAS	173.115
2	2.2	NON–FLAMMABLE COMPRESSED GAS	173.115
2	2.3	POISONOUS GAS	173.115
3		FLAMMABLE AND COMBUSTIBLE LIQUID	173.120
4	4.1	FLAMMABLE SOLID	173.124
4	4.2	SPONTANEOUSLY COMBUSTIBLE MATERIAL	173.124
4	4.3	DANGEROUS WHEN WET MATERIAL	173.124
5	5.1	OXIDIZER	173.127
5	5.2	ORGANIC PEROXIDE	173.128
6	6.1	POISONOUS MATERIALS	173.132
6	6.2	INFECTIOUS SUBSTANCE (ETIOLOGIC AGENT)	173.134
7		RADIOACTIVE MATERIAL	173.403
8		CORROSIVE MATERIAL	173.136
9		MISCELLANEOUS HAZARDOUS MATERIAL	173.140

■ 31. In § 173.4a, revise paragraph (g)(2) to read as follows:

§ 173.4a Excepted quantities.

* * * * *

(g) * * *

(2) The marking must be durable and clearly visible and in the form of a square. The hatching must be of the same color, black or red on white or a suitable contrasting background. The minimum dimensions must not be less than 100 mm (3.9 inches) by 100 mm (3.9 inches) as measured from the outside of the hatching forming the border. Where dimensions are not specified, all features shall be in approximate proportion to those shown. For domestic transportation, a packaging marked prior to January 1, 2017, and in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue in service until the end of its useful life.

* * * * *

■ 32. In 173.6, revise paragraphs (a)(1) introductory text and (a)(1)(ii) to read as follows:

§ 173.6 Materials of trade exceptions.

* * * * *

(a) * * *

(1) A Class 3, 8, 9, Division 4.1, 5.1, 5.2, or 6.1 material contained in a packaging having a gross mass or capacity not over—

* * * * *

(ii) 30 kg (66 pounds) or 30 L (8 gallons) for a Packing Group II or Packing Group III material;

* * * * *

■ 33. In § 173.11, revise paragraph (b) to read as follows:

§ 173.11 Exceptions for shipment of light bulbs containing hazardous materials.

* * * * *

(b) Light bulbs each containing not more than 1 g of hazardous materials and packaged so that there is not more than 30 g of hazardous materials per package. Each light bulb must be packed in inner packagings separated by dividers or surrounded by cushioning material to protect the light bulbs and packed into strong outer packagings meeting the requirements of § 173.24(b) of this subpart and capable of passing a 1.2 m (4 feet) drop test.

* * * * *

■ 34. In § 173.12, revise paragraph (h) to read as follows:

§ 173.12 Exceptions for shipment of waste materials.

* * * * *

(h) *Shrink-wrapped or stretch-wrapped pallets of limited quantity waste.* Shrink-wrapped or stretch-wrapped pallets containing packages of waste limited quantity materials may be transported by motor vehicle and cargo vessel under the following conditions:

(1) The waste materials must be in their original undamaged packaging marked with the authorized limited quantity marking in conformance with § 172.315 of this subchapter, as appropriate. The word ''waste'' in association with the proper shipping name is not required on individual packages;

(2) Packages must be securely affixed to a pallet and shrink-wrapped or stretch-wrapped;

(3) The outside of the shrink-wrap or stretch-wrap must be marked on opposite sides with ''Waste, Limited Quantity.''

■ 35. In § 173.24a, revise paragraph (c)(1)(iii) to read as follows:

§ 173.24a Additional general requirements for non-bulk packagings and packages.

* * * * *

(c) * * *

(1) * * *

(iii) Corrosive materials in bottles are further packed in securely closed inner receptacles before packing in outer packagings; and

* * * * *

■ 36. In § 173.25, revise paragraph (a)(4) to read as follows:

§ 173.25 Authorized packagings and overpacks.

(a) * * *

(4) The overpack is marked with the word ''OVERPACK'' when specification packagings are required, or for Class 7 (radioactive) material when a Type A, Type B(U), Type B(M) or industrial package is required. The ''OVERPACK'' marking is not required when the required markings representative of each package type contained in the overpack are visible from outside of the overpack. The lettering on the ''OVERPACK'' marking must be at least 12 mm (0.5 inches) high. For domestic transportation, an overpack marked prior to January 1, 2017, and in conformance with the requirements of this paragraph in effect on December 31, 2014, may continue in service until the end of its useful life.

* * * * *

■ 37. In § 173.27:

■ a. Revise table 2 to paragraph (f); and

■ b. Amend table 3 to paragraph (f) by revising the entry for ''Division 4.2 (Primary or subsidiary)''.

The revisions read as follows:

§ 173.27 General requirements for transportation by aircraft.

* * * * *

(f) * * *

(3) * * *

TABLE 2 TO PARAGRAPH (f)—MAXIMUM NET CAPACITY OF INNER PACKAGING FOR TRANSPORTATION ON CARGO AIRCRAFT

Maximum net quantity per package from Column 9b of § 172.101 table	Maximum authorized net capacity of each inner packaging	
	Glass, earthenware or fiber inner packagings	Metal or plastic inner packagings
Liquids:		
Not greater than 2.5L	1 L	1 L
Greater than 2.5L, not greater than 30L	2.5 L	2.5 L
Greater than 30L, not greater than 60L	5 L	10 L
Greater than 60L, not greater than 220L	5 L	25 L
Class 9: UN1941, UN1990, UN2315, UN3082, UN3151, UN3334	10 L	Plastic: 30 L Metal: 40 L
Solids:		
Not greater than 15 kg	1 kg	2.5 kg
Greater than 15 kg, not greater than 50 kg	2.5 kg	5 kg
Greater than 50 kg, not greater than 200 kg	5 kg	10 kg
Class 9: UN1841, UN1931, UN2071, UN2216, UN2590, UN2969, UN3077, UN3152, UN3335, UN3432.	Glass or earthenware: 10 kg Fiber: 50 kg	50 kg

TABLE 3 TO PARAGRAPH (f)—MAXIMUM NET QUANTITY OF EACH INNER AND OUTER PACKAGING FOR MATERIALS AUTHORIZED FOR TRANSPORTATION AS LIMITED QUANTITY BY AIRCRAFT

Hazard class or division	Maximum authorized net quantity of each inner packaging		Maximum authorized net quantity of each outer package	Notes
	Glass, earthenware, or fiber Inner packagings	Metal or plastic inner packagings		
*	*	*	*	*
Division 4.2 (Primary or subsidiary).	Forbidden *	*	25 kg (net mass) *	
*	*	*	*	*

* * * * *

■ 38. In § 173.29, revise paragraph (b)(2)(iv)(A) to read as follows:

§ 173.29 Empty packagings.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(A) A limited quantity material; or

* * * * *

■ 39. In § 173.36, revise paragraph (h)(1)(iii) to read as follows:

§ 173.36 Hazardous materials in Large Packagings.

* * * * *

(h) * * *

(1) * * *

(iii) Corrosive materials in bottles are further packed in securely closed inner receptacles before packing in outer packagings; and

* * * * *

■ 40. In § 173.62, amend Table 1 to Paragraph (b) by adding an entry for ''UN0485'' in appropriate alphanumerical order to read as follows:

§ 173.62 Specific packaging requirements for explosives.

* * * * *

(b) * * *

TABLE 1 TO PARAGRAPH (b)—EXPLOSIVE TABLE

ID No.	PI
* * * *	
UN0485	101
* * * *	

■ 41. In § 173.63, revise paragraph (b) to read as follows:

§ 173.63 Packaging exceptions.

* * * * *

(b) *Limited quantities of Cartridges, small arms, Cartridges, power device, Cartridges for tools, blank, and Cases, cartridge, empty with primer.*

(1)(i) Cartridges, small arms, Cartridges, power device (used to project fastening devices), Cartridges for tools, blank, and Cases, cartridge, empty with primer that have been classed as Division 1.4S explosive may be offered for transportation and transported as limited quantities when packaged in accordance with paragraph (b)(2) of this section. Packages containing such articles may be marked with either the marking prescribed in § 172.315(a) or (b) of this subchapter and offered for transportation and transported by any mode. For transportation by aircraft, the package must conform to the applicable requirements of § 173.27 of this part. In addition, packages containing such articles offered for transportation by aircraft must be marked with the proper shipping name as prescribed in the § 172.101 Hazardous Materials Table of this subchapter. Packages containing such articles are not subject to the shipping paper requirements of subpart C of part 172 of this subchapter unless the material meets the definition of a hazardous substance, hazardous waste, marine pollutant, or is offered for transportation and transported by aircraft or vessel. Additionally, packages containing such articles are excepted from the requirements of subparts E (Labeling) and F (Placarding) of part 172 of this subchapter.

(ii) Cartridges, small arms, Cartridges, power device (*used to project fastening devices*), Cartridges for tools, blank, and Cases, cartridge empty with primer that may be shipped as a limited quantity are as follows:

(A) Ammunition for rifle, pistol or shotgun;

(B) Ammunition with inert projectiles or blank ammunition;

(C) Ammunition having no tear gas, incendiary, or detonating explosive projectiles;

(D) Ammunition not exceeding 12.7 mm (50 caliber or 0.5 inch) for rifle or pistol, cartridges or 8 gauge for shotshells;

(E) Cartridges for tools, blank; and

(F) Cases, cartridge, empty with primer.

(G) Cartridges, power device (*used to project fastening devices*).

(2) Packaging for Cartridges, small arms, Cartridges for tools, blank, Cases, cartridge empty with primer, and eligible Cartridges, power device as limited quantity must be as follows:

(i) Ammunition must be packed in inside boxes, or in partitions that fit snugly in the outside packaging, or in metal clips;

(ii) Primers must be protected from accidental initiation;

(iii) Inside boxes, partitions or metal clips must be packed in securely-closed strong outside packagings;

(iv) Maximum gross weight is limited to 30 kg (66 pounds) per package; and

(v) Cartridges for tools, blank, Cartridges, power devices which are used to project fastening devices, Cases, cartridge, empty with primer, and 22 caliber rim-fire cartridges may be packaged loose in strong outside packagings.

* * * * *

§ 173.144 [Removed and Reserved]

■ 42. Remove and reserve § 173.144.

§ 173.145 [Removed and Reserved]

■ 43. Remove and reserve § 173.145.

§ 173.150 [Amended]

■ 44. In § 173.150, remove and reserve paragraph (c).

§ 173.151 [Amended]

■ 45. In § 173.151, remove and reserve paragraph (c).

§ 173.152 [Amended]

■ 46. In § 173.152, remove and reserve paragraph (c).

§ 173.153 [Amended]

■ 47. In § 173.153, remove and reserve paragraph (c).

§ 173.154 [Amended]

■ 48. In § 173.154, remove and reserve paragraph (c).

§ 173.155 [Amended]

■ 49. In § 173.155, remove and reserve paragraph (c).

■ 50. In § 173.156, revise the section heading, add a paragraph (a) subject heading, and revise paragraphs (b) introductory text, (b)(2) introductory text, and (d) to read as follows:

§ 173.156 Exceptions for limited quantity materials.

(a) *Applicability.* * * *

(b) *Additional packaging exceptions.* Packagings for limited quantity materials are specified according to hazard class in §§ 173.150 through 173.155, 173.306, and 173.309(b). In addition to exceptions provided for limited quantity materials elsewhere in this part, the following are provided:

* * * * *

(2) The 30 kg (66 pounds) gross weight limitation does not apply to packages of limited quantity materials marked in accordance with § 172.315 of this subchapter when offered for transportation or transported by highway or rail between a manufacturer, a distribution center, and a retail outlet provided—

* * * * *

(d) *Exceptions for waste limited quantity materials.* Exceptions for certain waste limited quantity materials are prescribed in § 173.12(h).

§ 173.161 [Amended]

■ 51. In § 173.161, remove paragraph (d)(2) and redesignate paragraph (d)(3) as paragraph (d)(2).

§ 173.165 [Amended]

■ 52. In § 173.165, remove and reserve paragraph (d).

■ 53. In § 173.185, revise paragraphs (b)(5), (c)(3) introductory text, (d), and (e)(5) to read as follows:

§ 173.185 Lithium cells and batteries.

* * * * *

(b) * * *

(5) Lithium batteries that weigh 12 kg (26.5 pounds) or more and have a strong, impact-resistant outer casing may be packed in strong outer packagings; in protective enclosures (for example, in fully enclosed or wooden slatted crates); or on pallets or other handling devices, instead of packages meeting the UN performance packaging requirements in paragraphs (b)(3)(ii) and (iii) of this section. Batteries must be secured to prevent inadvertent shifting, and the terminals may not support the weight of other superimposed elements. Batteries packaged in accordance with this paragraph may be transported by cargo aircraft if approved by the Associate Administrator.

* * * * *

(c) * * *

(3) *Lithium battery mark.* Each package must display the lithium battery mark except when a package contains button cell batteries installed in equipment (including circuit boards), or no more than four lithium cells or two lithium batteries contained in equipment, where there are not more than two packages in the consignment.

* * * * *

(d) *Lithium cells or batteries shipped for disposal or recycling.* A lithium cell or battery, including a lithium cell or battery contained in equipment, that is transported by motor vehicle to a permitted storage facility or disposal site, or for purposes of recycling, is excepted—

(1) From the testing and record keeping requirements of paragraph (a) and the UN performance packaging requirements in paragraphs (b)(3)(ii), (b)(3)(iii) and (b)(6) of this section, when packed in a strong outer packaging conforming to the applicable requirements of subpart B of this part; and

(2) From subparts C through H of part 172 of this subchapter when the lithium cell or battery meets the size, packaging, and hazard communication conditions in paragraph (c)(1)–(3) of this section.

(e) * * *

(5) Lithium batteries, including lithium batteries contained in equipment, that weigh 12 kg (26.5 pounds) or more and have a strong, impact-resistant outer casing may be packed in strong outer packagings, in protective enclosures (for example, in fully enclosed or wooden slatted crates), or on pallets or other handling devices, instead of packages meeting the UN performance packaging requirements in paragraphs (b)(3)(ii) and (iii) of this section. The battery must be secured to prevent inadvertent shifting, and the terminals may not support the weight of other superimposed elements;

* * * * *

■ 54. In § 173.225, in table 1 to paragraph (c), revise the following entries to read as follows:

§ 173.225 Packaging requirements and other provisions for organic peroxides.

* * * * *

(c) * * *

TABLE 1 TO PARAGRAPH (c):—ORGANIC PEROXIDE TABLE

Technical name	ID No.	Concentration (mass %)	Diluent (mass %)			Water (mass %)	Packing method	Temperature (°C)		Notes
			A	B	I			Control	Emergency	
(1)	(2)	(3)	(4a)	(4b)	(4c)	(5)	(6)	(7a)	(7b)	(8)
* * *		*		*		*		*		
tert-Amyl peroxy-2-ethylhexanoate	UN3115	≤100					OP7	+20	+25	
* * *		*		*		*		*		
tert-Amyl peroxyneodecanoate	UN3115	≤77		≥23			OP7	0	+10	
tert-Amyl peroxyneodecanoate	UN3119	≤47	≥53				OP8	0	+10	
tert-Amyl peroxypivalate	UN3113	≤77		≥23			OP5	+10	+15	
tert-Amyl peroxypivalate	UN3119	≤32	≥68				OP8	+10	+15	
* * *		*		*		*		*		
tert-Butyl peroxydiethylacetate	UN3113	≤100					OP5	+20	+25	
tert-Butyl peroxy-2-ethylhexanoate	UN3113	>52 – 100					OP6	+20	+25	
tert-Butyl peroxy-2-ethylhexanoate	UN3117	>32 – 52		≥48			OP8	+30	+35	
tert-Butyl peroxy-2-ethylhexanoate	UN3118	≤52			≥48		OP8	+20	+25	
tert-Butyl peroxy-2-ethylhexanoate	UN3119	≤32		≥68			OP8	+40	+45	
* * *		*		*		*		*		
tert-Butyl peroxy-2-ethylhexanoate [and] 2,2-di-(tert-Butylperoxy)butane	UN3115	≤31 + ≤36		≥33			OP7	+35	+40	
* * *		*		*		*		*		
tert-Butyl peroxyisobutyrate	UN3111	>52 – 77		≥23			OP5	+15	+20	
tert-Butyl peroxyisobutyrate	UN3115	≤52		≥48			OP7	+15	+20	
* * *		*		*		*		*		
tert-Butyl peroxyneodecanoate	UN3115	>77 – 100					OP7	−5	+5	
tert-Butyl peroxyneodecanoate	UN3115	≤77		≥23			OP7	0	+10	
tert-Butyl peroxyneodecanoate [as a stable dispersion in water]	UN3119	≤52					OP8	0	+10	
tert-Butyl peroxyneodecanoate [as a stable dispersion in water (frozen)]	UN3118	≤42					OP8	0	+10	
tert-Butyl peroxyneodecanoate	UN3119	≤32	≥68				OP8	0	+10	
tert-Butyl peroxyneoheptanoate	UN3115	≤77	≥23				OP7	0	+10	
tert-Butyl peroxyneoheptanoate [as a stable dispersion in water]	UN3117	≤42					OP8	0	+10	
tert-Butyl peroxypivalate	UN3113	>67 – 77	≥23				OP5	0	+10	
tert-Butyl peroxypivalate	UN3115	>27 – 67		≥33			OP7	0	+10	

TABLE 1 TO PARAGRAPH (c):—ORGANIC PEROXIDE TABLE—Continued

Technical name	ID No.	Concentration (mass %)	Diluent (mass %)			Water (mass %)	Packing method	Temperature (°C)		Notes
			A	B	I			Control	Emergency	
(1)	(2)	(3)	(4a)	(4b)	(4c)	(5)	(6)	(7a)	(7b)	(8)
tert-Butyl peroxypivalate	UN3119	≤27		≥73			OP8	+30	+35	
* * *	*		*		*		*			
Cumyl peroxypivalate	UN3115	≤77		≥23			OP7	−5	+5	
* * *	*		*		*		*			
Diacetone alcohol peroxides	UN3115	≤57		≥26		≥8	OP7	+40	+45	5
Diacetyl peroxide	UN3115	≤27		≥73			OP7	+20	+25	8,13
* * *	*		*		*		*			
Di-(4-tert-butylcyclohexyl)peroxydicarbonate	UN3114	≤100					OP6	+30	+35	
Di-(4-tert-butylcyclohexyl)peroxydicarbonate [as a stable dispersion in water]	UN3119	≤42					OP8	+30	+35	
Di-(4-tert-butylcyclohexyl)peroxydicarbonate [as a paste]	UN3116	≤42					OP7	+35	+40	
* * *	*		*		*		*			
Dicetyl peroxydicarbonate	UN3120	≤100					OP8	+30	+35	
Dicetyl peroxydicarbonate [as a stable dispersion in water]	UN3119	≤42					OP8	+30	+35	
* * *	*		*		*		*			
Di-2,4-dichlorobenzoyl peroxide [as a paste]	UN3118	≤52					OP8	+20	+25	
* * *	*		*		*		*			
Dicyclohexyl peroxydicarbonate	UN3112	>91−100					OP3	+10	+15	
Dicyclohexyl peroxydicarbonate	UN3114	≤91				≥9	OP5	+10	+15	
Dicyclohexyl peroxydicarbonate [as a stable dispersion in water]	UN3119	≤42					OP8	+15	+20	
Didecanoyl peroxide	UN3114	≤100					OP6	+30	+35	
* * *	*		*		*		*			
Di-(3-methoxybutyl) peroxydicarbonate	UN3115	≤52		≥48			OP7	−5	+5	
Di-(2-methylbenzoyl)peroxide	UN3112	≤87				≥13	OP5	+30	+35	
* * *	*		*		*		*			
Di-(3-methylbenzoyl) peroxide + Benzoyl (3-methylbenzoyl) peroxide + Dibenzoyl peroxide	UN3115	≤20 + ≤18 + ≤4		≥58			OP7	+35	+40	
* * *	*		*		*		*			
2,5-Dimethyl-2,5-di-(2-ethylhexanoylperoxy)hexane	UN3113	≤100					OP5	+20	+25	
* * *	*		*		*		*			
1,1-Dimethyl-3-hydroxybutylperoxyneoheptanoate	UN3117	≤52	≥48				OP8	0	+10	
Dimyristyl peroxydicarbonate	UN3116	≤100					OP7	+20	+25	
Dimyristyl peroxydicarbonate [as a stable dispersion in water]	UN3119	≤42					OP8	+20	+25	
* * *	*		*		*		*			
Di-n-nonanoyl peroxide	UN3116	≤100					OP7	0	+10	
Di-n-octanoyl peroxide	UN3114	≤100					OP5	+10	+15	
* * *	*		*		*		*			
Dipropionyl peroxide	UN3117	≤27		≥73			OP8	+15	+20	
* * *	*		*		*		*			
Disuccinic acid peroxide	UN3116	≤72				≥28	OP7	+10	+15	
Di-(3,5,5-trimethylhexanoyl) peroxide	UN3115	>52−82	≥18				OP7	0	+10	
Di-(3,5,5-trimethylhexanoyl)peroxide [as a stable dispersion in water]	UN3119	≤52					OP8	+10	+15	
Di-(3,5,5-trimethylhexanoyl) peroxide	UN3119	>38−52	≥48				OP8	+10	+15	
Di-(3,5,5-trimethylhexanoyl)peroxide	UN3119	≤38	≥62				OP8	+20	+25	
* * *	*		*		*		*			
tert-Hexyl peroxyneodecanoate	UN3115	≤71	≥29				OP7	0	+10	
tert-Hexyl peroxypivalate	UN3115	≤72		≥28			OP7	+10	+15	
3-Hydroxy-1,1-dimethylbutyl peroxyneodecanoate	UN3115	≤77	≥23				OP7	−5	+5	
3-Hydroxy-1,1-dimethylbutyl peroxyneodecanoate [as a stable dispersion in water]	UN3119	≤52					OP8	−5	+5	
3-Hydroxy-1,1-dimethylbutyl peroxyneodecanoate	UN3117	≤52	≥48				OP8	−5	+5	
* * *	*		*		*		*			
Methylcyclohexanone peroxide(s)	UN3115	≤67		≥33			OP7	+35	+40	
* * *	*		*		*		*			
Peroxylauric acid	UN3118	≤100					OP8	+35	+40	

TABLE 1 TO PARAGRAPH (c):—ORGANIC PEROXIDE TABLE—Continued

Technical name	ID No.	Concentration (mass %)	Diluent (mass %)			Water (mass %)	Packing method	Temperature (°C)		Notes
			A	B	I			Control	Emergency	
(1)	(2)	(3)	(4a)	(4b)	(4c)	(5)	(6)	(7a)	(7b)	(8)
* *	*	*		*		*		*		
1,1,3,3-Tetramethylbutyl peroxy-2-ethylhexanoate	UN3115	≤100					OP7	+15	+20	
1,1,3,3-Tetramethylbutyl peroxyneodecanoate	UN3115	≤72		≥28			OP7	−5	+5	
1,1,3,3-Tetramethylbutyl peroxyneodecanoate [as a stable dispersion in water]	UN3119	≤52					OP8	−5	+5	
1,1,3,3-tetramethylbutyl peroxypivalate	UN3115	≤77	≥23				OP7	0	+10	
* *	*	*		*		*		*		

* * * * *

§ 173.230 [Amended]

■ 55. In § 173.230, remove and reserve paragraph (h).

■ 56. In § 173.244, revise paragraph (a)(2) introductory text to read as follows:

§ 173.244 Bulk packaging for certain pyrophoric liquids (Division 4.2), dangerous when wet (Division 4.3) materials, and poisonous liquids with inhalation hazards (Division 6.1).

* * * * *

(a) * * *

(2) For materials poisonous by inhalation, until December 31, 2027, single unit tank car tanks built prior to March 16, 2009, and approved by the Tank Car Committee for transportation of the specified material. Except as provided in paragraph (a)(3) of this section, tank cars built on or after March 16, 2009, used for the transportation of the PIH materials listed below, must meet the applicable authorized tank car specification listed in the following table:

* * * * *

■ 57. In § 173.301, revise paragraph (f)(5) to read as follows:

§ 173.301 General requirements for shipment of compressed gases and other hazardous materials in cylinders, UN pressure receptacles and spherical pressure vessels.

* * * * *

(f) * * *

(5) A pressure relief device is not required on—

(i) A cylinder 305 mm (12 inches) or less in length, exclusive of neck, and 114 mm (4.5 inches) or less in outside diameter, except when the cylinder is filled with a liquefied gas for which this part requires a service pressure of 1800 psig or higher or a nonliquefied gas to a pressure of 1800 psig or higher at 21 °C (70 °F);

(ii) A cylinder with a water capacity of less than 454 kg (1000 lbs.) filled with a nonliquefied gas to a pressure of 300 psig or less at 21 °C (70 °F), except for a DOT 39 cylinder or a cylinder used for acetylene in solution;

(iii) A cylinder containing a Class 3 or a Class 8 material without pressurization, unless otherwise specified for the hazardous material; or

(iv) A UN pressure receptacle transported in accordance with paragraph (k) or (l) of this section.

* * * * *

■ 58. In § 173.303, revise paragraph (f)(1)(i) to read as follows:

§ 173.303 Charging of cylinders with compressed gas in solution (acetylene).

* * * * *

(f) * * *

(1) * * *

(i) Each UN acetylene cylinder must conform to ISO 3807:2013(E): (IBR, see § 171.7 of this subchapter), have a homogeneous monolithic porous mass filler and be charged with acetone or a suitable solvent as specified in the standard. UN acetylene cylinders must have a minimum test pressure of 52 bar and may be filled up to the pressure limits specified in ISO 3807:2013(E). The use of UN tubes and MEGCs is not authorized.

* * * * *

■ 59. In § 173.304a, revise (a)(2) to read as follows:

§ 173.304a Additional requirements for shipment of liquefied compressed gases in specification cylinders.

(a) * * *

(2) For the gases named, the requirements in table 1 to paragraph (a)(2) apply (for cryogenic liquids, *see* § 173.316):

TABLE 1 TO PARAGRAPH (a)(2)

Kind of gas	Maximum permitted filling density (percent) (see Note 1)	Packaging marked as shown in this column or of the same type with higher service pressure must be used, except as provided in §§ 173.301(l), 173.301a(e), and 180.205(a) (see the following notes after the table)
Anhydrous ammonia	54	DOT–3A480; DOT–3AA480; DOT–3A480X; DOT–4AA480; DOT–3; DOT–3E1800; DOT–3AL480.
Bromotrifluoromethane (R–13B1 or H–1301).	124	DOT–3A400; DOT–3AA400; DOT–3B400; DOT–4AA480; DOT–4B400; DOT–4BA400; DOT–4BW400; DOT–3E1800; DOT–39; DOT–3AL400.
Carbon dioxide (see Notes 4, 7, and 8).	68	DOT–3A1800; DOT–3AX1800; DOT–3AA1800; DOT–3AAX1800; DOT–3; DOT–3E1800; DOT–3T1800; DOT–3HT2000; DOT–39; DOT–3AL1800.
Carbon dioxide (see Notes 4, 7, and 8).	70.3	DOT–3A2000, DOT–3AA2000, DOT–3AX2000, DOT–3AAX2000, DOT–3T2000.
Carbon dioxide (see Notes 4, 7, and 8).	73.2	DOT–3A2265, DOT–3AA2265, DOT–3AX2265, DOT–3AAX2265, DOT–3T2265.
Carbon dioxide (see Notes 4, 7, and 8).	74.5	DOT–3A2400, DOT–3AA2400, DOT–3AX2400, DOT–3AAX2400, DOT–3T2400.

TABLE 1 TO PARAGRAPH (a)(2)—Continued

Kind of gas	Maximum permitted filling density (percent) (see Note 1)	Packaging marked as shown in this column or of the same type with higher service pressure must be used, except as provided in §§ 173.301(l), 173.301a(e), and 180.205(a) (see the following notes after the table)
Carbon dioxide, refrigerated liquid (see *paragraph (e)* of this section).	.....	DOT–4L.
Chlorine (see Note 2)	125	DOT–3A480; DOT–3AA480; DOT–3; DOT–3BN480; DOT–3E1800.
Chlorodifluroethane or 1-Chloro-1, 1-difluoroethane (R–142b).	100	DOT–3A150; DOT–3AA150; DOT–3B150; DOT–4B150; DOT–4BA225; DOT–4BW225; DOT–3E1800; DOT–39; DOT–3AL150.
Chlorodifluoromethane (R–22) (see Note 8).	105	DOT–3A240; DOT–3AA240; DOT–3B240; DOT–4B240; DOT–4BA240; DOT–4BW240; DOT–4B240ET; DOT–4E240; DOT–39; DOT–3E1800; DOT–3AL240.
Chloropentafluorethane (R–115).	110	DOT–3A225; DOT–3AA225; DOT–3B225; DOT–4BA225; DOT–4B225; DOT–4BW225; DOT–3E1800; DOT–39; DOT–3AL225.
Chlorotrifluoromethane (R–13) (see Note 8).	100	DOT–3A1800; DOT–3AA1800; DOT–3; DOT–3E1800; DOT–39; DOT–3AL1800.
Cyclopropane (see Notes 8 and 9).	55	DOT–3A225; DOT–3A480X; DOT–3AA225; DOT–3B225; DOT–4AA480; DOT4B225; DOT–4BA225; DOT–4BW225; DOT–4B240ET; DOT–3; DOT–3E1800; DOT–39; DOT–3AL225.
Dichlorodifluoromethane (R–12) (see Note 8).	119	DOT–3A225; DOT–3AA225; DOT–3B225; DOT–4B225; DOT–4BA225; DOT–4BW225; DOT–4B240ET; DOT–4E225; DOT–39; DOT–3E1800; DOT–3AL225.
Dichlorodifluoromethane and difluoroethane mixture (constant boiling mixture) (R–500) (see Note 8).	Not liquid full at 131 °F.	DOT–3A240; DOT–3AA240; DOT–3B240; DOT–3E1800; DOT–4B240; DOT–4BA240; DOT–4BW240; DOT–4E240; DOT–39.
1,1-Difluoroethane (R–152a) (see Note 8).	79	DOT–3A150; DOT–3AA150; DOT–3B150; DOT–4B150; DOT–4BA225; DOT–4BW225; DOT–3E1800; DOT–3AL150.
1,1-Difluoroethylene (R–1132A).	73	DOT–3A2200; DOT–3AA2200; DOT–3AX2200; DOT–3AAX2200; DOT–3T2200; DOT–39.
Dimethylamine, anhydrous	59	DOT–3A150; DOT–3AA150; DOT–3B150; DOT–4B150; DOT–4BA225; DOT–4BW225; ICC–3E1800.
Ethane (see Notes 8 and 9).	35.8	DOT–3A1800; DOT–3AX1800; DOT–3AA1800; DOT–3AAX1800; DOT–3; DOT–3E1800; DOT–3T1800; DOT–39; DOT–3AL1800.
Ethane (see Notes 8 and 9).	36.8	DOT–3A2000; DOT–3AX2000; DOT–3AA2000; DOT–3AAX2000; DOT–3T2000; DOT–39; DOT–3AL2000
Ethylene (see Notes 8 and 9)..	31.0	DOT–3A1800; DOT–3AX1800; DOT–3AA1800; DOT–3AAX1800; DOT–3; DOT–3E1800; DOT–3T1800; DOT–39; DOT–3AL1800.
Ethylene (see Notes 8 and 9).	32.5	DOT–3A2000; DOT–3AX2000; DOT–3AA2000; DOT–3AAX2000; DOT–3T2000; DOT–39; DOT–3AL2000.
Ethylene (see Notes 8 and 9).	35.5	DOT–3A2400; DOT–3AX2400; DOT–3AA2400; DOT–3AAX2400; DOT–3T2400; DOT–39; DOT–3AL2400.
Hydrogen chloride, anhydrous.	65	DOT–3A1800; DOT–3AA1800; DOT–3AX1800; DOT–3AAX1800; DOT–3; DOT–3T1800; DOT–3E1800.
Hydrogen sulfide (Note 10)	62.5	DOT–3A; DOT–3AA; DOT–3B; DOT–4B; DOT–4BA; DOT–4BW; DOT–3E1800; DOT–3AL.
Insecticide, gases liquefied (see Notes 8 and 12).	Not liquid full at 131 °F.	DOT–3A300; DOT–3AA300; DOT–3B300; DOT–4B300; DOT–4BA300; DOT–4BW300; DOT–3E1800.
Liquefied nonflammable gases, other than classified flammable, corrosive, toxic & mixtures or solution thereof filled w/ nitrogen, carbon dioxide, or air (see Notes 7 and 8)..	Not liquid full at 131 °F.	Specification packaging authorized in *paragraph (a)(1)* of this section and DOT–3HT; DOT–4D; DOT–4DA; DOT–4DS.
Methyl acetylene and propadiene mixtures, stabilized; (see Note 5)..	Not liquid full at 131 °F.	DOT–4B240 without brazed seams; DOT–4BA240 without brazed seams; DOT–3A240; DOT–3AA240; DOT–3B240; DOT–3E1800; DOT–4BW240; DOT–4E240; DOT–4B240ET; DOT–3AL240.
Methyl chloride	84	DOT–3A225; DOT–3AA225; DOT–3B225; DOT–4B225; DOT–4BA225; DOT–4BW225; DOT–3; DOT–3E1800; DOT–4B240ET. Cylinders complying with DOT–3A150; DOT–3B150; and DOT–4B150 manufactured prior to Dec. 7, 1936 are also authorized.
Methyl mercaptan	80	DOT–3A240; DOT–3AA240; DOT–3B240; DOT–4B240; DOT–4B240ET; DOT–3E1800; DOT–4BA240; DOT–4BW240.
Nitrosyl chloride	110	DOT–3BN400 only.
Nitrous oxide (see Notes 7, 8, and 11).	68	DOT–3A1800; DOT–3AX1800; DOT–3AA1800; DOT–3AAX1800; DOT–3; DOT–3E1800; DOT–3T1800; DOT–3HT2000; DOT–39; DOT–3AL1800.
Nitrous oxide (see Notes 7, 8, and 11).	70.3	DOT–3A2000, DOT–3AA2000, DOT–3AX2000, DOT–3AAX2000, DOT–3T2000.
Nitrous oxide (see Notes 7, 8, and 11).	73.2	DOT–3A2265, DOT–3AA2265, DOT–3AX2265, DOT–3AAX2265, DOT–3T2265.
Nitrous oxide (see Notes 7, 8, and 11).	74.5	DOT–3A2400, DOT–3AA2400, DOT–3AX2400, DOT–3AAX2400, DOT–3T2400.

TABLE 1 TO PARAGRAPH (a)(2)—Continued

Kind of gas	Maximum permitted filling density (percent) (see Note 1)	Packaging marked as shown in this column or of the same type with higher service pressure must be used, except as provided in §§ 173.301(l), 173.301a(e), and 180.205(a) (see the following notes after the table)
Nitrous oxide, refrigerated liquid (see *paragraph (e)* of this section.).	.....	DOT–4L.
Refrigerant gas, n.o.s. or Dispersant gas, n.o.s. (see Notes 8 and 13).	Not liquid full at 130 °F.	DOT–3A240; DOT–3AA240; DOT–3B240; DOT–3E1800; DOT–4B240; DOT–4BA240; DOT–4BW240; DOT–4E240; DOT–39; DOT–3AL240.
Sulfur dioxide (see note 8)	125	DOT–3A225; DOT–3AA225; DOT–3B225; DOT–4B225; DOT–4BA225; DOT–4BW225; DOT–4B240ET; DOT–3; DOT–39; DOT–3E1800; DOT–3AL225.
Sulfur hexafluoride	120	DOT–3A1000; DOT–3AA1000; DOT–AAX2400; DOT–3; DOT–3AL1000; DOT–3E1800; DOT–3T1800.
Sulfuryl fluoride	106	DOT–3A480; DOT–3AA480; DOT–3E1800; DOT–4B480; DOT–4BA480; DOT–4BW480.
Tetrafluoroethylene, stabilized.	90	DOT–3A1200; DOT–3AA1200; DOT–3E1800.
Trifluorochloroethylene, stabilized.	115	DOT–3A300; DOT–3AA300; DOT–3B300; DOT–4B300; DOT–4BA300; DOT–4BW300; DOT–3E1800.
Trimethylamine, anhydrous	57	DOT–3A150; DOT–3AA150; DOT–3B150; DOT–4B150; DOT–4BA225; DOT–4BW225; DOT–3E1800.
Vinyl chloride (see Note 5)	84	DOT–4B150 without brazed seams; DOT–4BA225 without brazed seams; DOT–4BW225; DOT–3A150; DOT–3AA150; DOT–3E1800; DOT–3AL150.
Vinyl fluoride, stabilized	62	DOT–3A1800; DOT–3AA1800; DOT–3E1800; DOT–3AL1800.
Vinyl methyl ether, stabilized (see Note 5).	68	DOT–4B150, without brazed seams; DOT–4BA225 without brazed seams; DOT–4BW225; DOT–3A150; DOT–3AA150; DOT–3B1800; DOT–3E1800.

Note 1 to paragraph (a)(2): ''Filling density'' means the percent ratio of the weight of gas in a packaging to the weight of water that the container will hold at 16 °C (60 °F). (1 lb. of water = 27.737 in^3 at 60 °F).

Note 2 to paragraph (a)(2): Cylinders purchased after Oct. 1, 1944, for the transportation of chlorine must contain no aperture other than that provided in the neck of the cylinder for attachment of a valve equipped with an approved pressure relief device. Cylinders purchased after November 1, 1935, and filled with chlorine may not contain over 68.04 kg (150 lb.) of gas.

Note 4 to paragraph (a)(2): Special carbon dioxide mining devices containing a heating element and filled with not over 2.72 kg (6 lb.) of carbon dioxide may be filled to a density of not over 85 percent, provided the cylinder is made of steel with a calculated bursting pressure in excess of 39,000 psig, fitted with a frangible disc that will operate at not over 57 percent of that pressure, and is able to withstand a drop of 10 feet when striking crosswise on a steel rail while under a pressure of at least 3,000 psig. Such devices must be shipped in strong boxes or must be wrapped in heavy burlap and bound by 12-gauge wire with the wire completely covered by friction tape. Wrapping must be applied so as not to interfere with the functioning of the frangible disc pressure relief device. Shipments must be described as ''liquefied carbon dioxide gas (mining device)'' and marked, labeled, and certified as prescribed for liquefied carbon dioxide.

Note 5 to paragraph (a)(2): All parts of the valve and pressure relief devices in contact with contents of cylinders must be of a metal or other material, suitably treated, if necessary, that will not cause the formation of any acetylides.

Note 7 to paragraph (a)(2): Specification 3HT cylinders for aircraft use only, having a maximum service life of 24 years. Authorized only for nonflammable gases. Cylinders must be equipped with pressure relief devices of the frangible disc type that meet the requirements of § 173.301(f). Each frangible disc must have a rated bursting pressure that does not exceed 90 percent of the minimum required test pressure of the cylinder. Discs with fusible metal backing are not permitted. Cylinders may be offered for transportation only when packaged in accordance with § 173.301(a)(9).

Note 8 to paragraph (a)(2): See § 173.301(a)(9).

Note 9 to paragraph (a)(2): When used for shipment of flammable gases, the internal volume of a specification 39 cylinder must not exceed 75 cubic inches.

Note 10 to paragraph (a)(2): Each valve outlet must be sealed by a threaded cap or a threaded solid plug.

Note 11 to paragraph (a)(2): Must meet the valve and cleaning requirements in § 173.302(b).

Note 12 to paragraph (a)(2): For an insecticide gas that is nontoxic and nonflammable, see § 173.305(c).

Note 13 to paragraph (a)(2): For a refrigerant or dispersant gas that is nontoxic and nonflammable, see § 173.304(d).

* * * * *

■ 60. In § 173.306, revise paragraphs (a)(1), (b) introductory text, (h)(2)(i), and (i) to read as follows:

§ 173.306 Limited quantities of compressed gases.

(a) * * *

(1) When in containers of not more than 4 fluid ounces capacity (7.22 cubic inches or less) except cigarette lighters. Additional exceptions for certain compressed gases in limited quantities are provided in paragraph (i) of this section.

* * * * *

(b) *Exceptions for foodstuffs, soap, biologicals, electronic tubes, and audible fire alarm systems.* Limited quantities of compressed gases (except Division 2.3 gases) for which exceptions are provided as indicated by reference to this section in § 172.101 of this subchapter, when in conformance with one of the following paragraphs, are excepted from labeling, except when offered for transportation or transported by aircraft, and the specification packaging requirements of this subchapter. For transportation by aircraft, the package must conform to the applicable requirements of § 173.27 and only packages of hazardous materials authorized aboard passenger-carrying aircraft may be transported as a limited quantity. In addition, shipments are not subject to subpart F (Placarding) of part 172 of this subchapter, to part 174 of this subchapter, except § 174.24, and to part 177 of this subchapter, except § 177.817. Additional exceptions for certain compressed gases in limited quantities

are provided in paragraph (i) of this section.

* * * * *

(h) * * *

(2) * * *

(i) For other than transportation by aircraft, exceptions for certain compressed gases in limited quantities are provided in paragraph (i) of this section.

* * * * *

(i) *Limited quantities.* A limited quantity that conforms to the provisions of paragraph (a)(1), (a)(3), (a)(5), (b) or, except for transportation by aircraft, paragraph (h) of this section is excepted from labeling requirements, unless the material is offered for transportation or transported by aircraft, and the specification packaging requirements of this subchapter when packaged in combination packagings according to this paragraph. Packages must be marked in accordance with § 172.315(a) or (b), as appropriate. Packages of limited quantities intended for transportation by aircraft must conform to the applicable requirements (*e.g.,* authorized materials, inner packaging quantity limits, and closure securement) of § 173.27 of this part. A limited quantity package that conforms to the provisions of this section is not subject to the shipping paper requirements of subpart C of part 172 of this subchapter, unless the material meets the definition of a hazardous substance, hazardous waste, marine pollutant, or is offered for transportation and transported by aircraft or vessel and is eligible for the exceptions provided in § 173.156 of this part. Outside packagings conforming to this paragraph are not required to be marked ''INSIDE CONTAINERS COMPLY WITH PRESCRIBED REGULATIONS.'' In addition, packages of limited quantities are not subject to subpart F (Placarding) of part 172 of this subchapter. Each package must conform to the packaging requirements of subpart B of this part and may not exceed 30 kg (66 pounds) gross weight.

* * * * *

■ 61. In § 173.313, revise the introductory text to read as follows:

§ 173.313 UN Portable Tank Table for Liquefied Compressed Gases and Chemical under Pressure.

The UN Portable Tank Table for Liquefied Compressed Gases and chemical under pressure is referenced in § 172.102(c)(7)(iii) of this subchapter for portable tanks that are used to transport liquefied compressed gases and chemicals under pressure. The table applies to each liquefied compressed gas and chemical under pressure that is identified with Special Provision T50 in Column (7) of the Hazardous Materials Table in § 172.101. In addition to providing the UN identification number and proper shipping name, the table provides the minimum design pressures, bottom opening requirements, pressure relief device requirements, and degree of filling requirements for liquefied compressed gases and chemicals under pressure permitted for transportation in a T50 portable tank. In the minimum design pressure column, ''small'' means a portable tank with a diameter of 1.5 meters or less when measured at the widest part of the shell, ''sunshield'' means a portable tank with a shield covering at least the upper third of the shell, ''bare'' means no sunshield or insulation is provided, and ''insulated'' means a complete cladding of sufficient thickness of insulating material necessary to provide a minimum conductance of not more than 0.67 w/m2/k. In the pressure relief requirements column, the word ''Normal'' denotes that a frangible disc as specified in § 178.276(e)(3) of this subchapter is not required.

* * * * *

■ 62. In § 173.314, revise notes 1 through 12 to Table 1 to Paragraph (c) to read as follows:

§ 173.314 Compressed gases in tank cars and multi-unit tank cars.

* * * * *

(c) * * *

Table 1 to Paragraph (c)

* * * * *

Notes to table 1 to paragraph (c): 1. The filling density percentage for liquefied gases is hereby defined as the percent ratio of the mass of gas in the tank to the mass of water that the tank will hold. For determining the water capacity of the tank in kilograms, the mass of 1 L of water at 15.5 °C in air is 1 kg (the mass of one gallon of water at 60 °F in air is 8.32828 pounds).

2. The liquefied gas must be loaded so that the outage is at least two percent of the total capacity of the tank at the reference temperature of 46 °C (115 °F) for a non-insulated tank; 43 °C (110 °F) for a tank having a thermal protection system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 10.22 kilojoules per hour—per square meter—per degree Celsius (0.5 Btu per hour/per square foot/per degree F) temperature differential; and 41 °C (105 °F) for an insulated tank having an insulation system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 1.5333 kilojoules per hour—per square meter—per degree Celsius (0.075 Btu per hour/per square foot/per degree F) temperature differential.

3. The requirements of § 173.24b(a) apply.

4. The gas pressure at 54.44 °C (130 °F) in any non-insulated tank car may not exceed 7/10 of the marked test pressure, except that a tank may be charged with helium to a pressure of 10 percent in excess of the marked maximum gas pressure at 54.44 °C (130 °F) of each tank.

5. The liquid portion of the gas at −17.77 °C (0 °F) must not completely fill the tank.

6. The maximum permitted filling density is 125 percent. The quantity of chlorine loaded into a single unit-tank car may not be loaded in excess of the normal lading weights nor in excess of 81.65 Mg (90 tons).

7. 89 percent maximum to 80.1 percent minimum at a test pressure of 6.2 bar (90 psig).

8. 59.6 percent maximum to 53.6 percent minimum at a test pressure of 7.2 bar (105 psig).

9. For a liquefied petroleum gas, the liquefied gas must be loaded so that the outage is at least one percent of the total capacity of the tank at the reference temperature of 46 °C (115 °F) for a non-insulated tank; 43 °C (110 °F) for a tank having a thermal protection system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 10.22 kilojoules per hour—per square meter—per degree Celsius (0.5 Btu per hour/per square foot/per degree F) temperature differential; and 41 °C (105 °F) for an insulated tank having an insulation system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 1.5333 kilojoules per hour—per square meter—per degree Celsius (0.075 Btu per hour/per square foot/per degree F) temperature differential.

10. For liquefied petroleum gas and anhydrous ammonia, during the months of November through March (winter), the following reference temperatures may be used: 38 °C (100 °F) for a non-insulated tank; 32 °C (90 °F) for a tank having a thermal protection system incorporating a metal jacket that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 10.22 kilojoules per hour—per square meter—per degree Celsius (0.5 Btu per hour/per square foot/per degree F) temperature differential; and 29 °C (85 °F) for an insulated tank having an insulation system incorporating a metal jacket and insulation that provides an overall thermal conductance at 15.5 °C (60 °F) of no more than 1.5333 kilojoules per hour—per square meter—per degree Celsius (0.075 Btu per hour/per square foot/per degree F) temperature differential. The winter reference temperatures may only be used for a tank car shipped directly to a consumer for unloading and not stored in transit. The offeror of the tank must inform each customer that the tank car was filled based on winter reference temperatures. The tank must be unloaded as soon as possible after March in order to retain the specified outage and to prevent a release of hazardous material, which might occur due to the tank car becoming liquid full at higher temperatures.

11. For materials poisonous by inhalation, until December 31, 2027, the single unit tank car tanks authorized are only those cars approved by the Tank Car Committee for

transportation of the specified material and built prior to March 16, 2009. After December 31, 2027, all single unit tank cars used in PIH/TIH service must meet the requirements of Note 12.

12. Except as provided in paragraph (d) of this section, for materials poisonous by inhalation, fusion-welded tank car tanks built on or after March 16, 2009, used for the transportation of the PIH materials noted, must meet the applicable authorized tank car specification and must be equipped with a head shield as prescribed in § 179.16(c)(1).

* * * * *

§ 173.315 [Amended]

■ 63. In § 173.315, redesignate paragraph (j)(3) as paragraph (j)(1)(iv).

PART 174—CARRIAGE BY RAIL

■ 64. The authority citation for part 174 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 33 U.S.C. 1321; 49 CFR 1.81 and 1.97.

■ 65. Revise § 174.5 to read as follows:

§ 174.5 Carrier's materials and supplies.

This subchapter applies to the transportation of a carrier's materials and supplies moving by rail, except that the shipper's certification is not required when these materials and supplies are being transported by the carrier who owns them. The requirements of this subchapter do not apply to railway torpedoes or railroad safety flares (*i.e.,* fusees) when carried in engines or rail cars. Railway torpedoes must be in closed metal boxes when not in use.

■ 66. In § 174.55, revise paragraph (a) to read as follows:

§ 174.55 General requirements.

(a) Each package containing a hazardous material being transported by rail in a freight container or transport vehicle must be loaded so that it cannot fall or slide and must be safeguarded in such a manner that other freight cannot fall onto or slide into it under conditions normally incident to transportation. When this protection cannot be provided by using other freight, it must be provided by blocking and bracing. For examples of blocking and bracing in freight containers and transport vehicles, see the Intermodal Loading Guide for Products in Closed Trailers and Containers (see table 1 to § 171.7 of this subchapter).

* * * * *

■ 67. In § 174.67, revise paragraph (a)(3) to read as follows:

§ 174.67 Tank car unloading.

* * * * *

(a) * * *

(3) Each hazmat employee who is responsible for unloading must secure access to the track to prevent entry by other rail equipment, including motorized service vehicles. This requirement may be satisfied by lining each switch providing access to the unloading area against motion and securing each switch with an effective locking device, or by using derails, portable bumper blocks, or other equipment that provides an equivalent level of safety.

* * * * *

■ 68. In § 174.82, revise paragraph (a) to read as follows:

§ 174.82 General requirements for the handling of placarded rail cars, transport vehicles, freight containers, and bulk packages.

(a) Unless otherwise specified, this subpart does not apply to the handling of rail cars, transport vehicles, freight containers, or bulk packagings, which contain Division 1.6, combustible liquids, Division 6.1 PG III materials, or Class 9 materials.

* * * * *

■ 69. In § 174.101, revise paragraph (h) to read as follows:

§ 174.101 Loading Class 1 (explosive) materials.

* * * * *

(h) Packages containing any Division 1.1 or 1.2 (explosive) materials for (see § 174.104), detonators, detonator assemblies, or boosters with detonators must be securely blocked and braced to prevent the packages from changing position, falling to the floor, or sliding into each other, under conditions normally incident to transportation. Class 1 (explosive) materials must be loaded so as to avoid transfer at stations. For recommended methods of blocking and bracing, see the Intermodal Loading Guide for Products in Closed Trailers and Containers (see Table 1 to § 171.7 of this subchapter). Heavy packages or containers must be trucked, rolled, or moved by skids, fork trucks, or other handling devices and may not be dropped from trucks, platforms, or cars. Planks for rolling trucks from platforms to cars must have beveled ends. Loading platforms and the shoes of each workman must be free from grit. All possible precautions must be taken against fire. Class 1 (explosive) materials must be kept in a safe place and inaccessible to unauthorized persons while being held by a carrier for loading or delivery.

* * * * *

■ 70. In § 174.112, revise paragraph (b) to read as follows:

§ 174.112 Loading Division 1.3 materials and Division 1.2 (explosive) materials (Also see § 174.101).

* * * * *

(b) Except as provided in § 174.101(b), (n), or (o), Division 1.3 materials and Division 1.2 (explosive) materials must be transported in a closed car or container car which is in good condition, and into which sparks cannot enter. The car does not require the car certificates prescribed in § 174.104(c) through (f). If the doors are not tight, they must be stripped to prevent the entrance of sparks. Wood floored cars must be equipped with spark shields (*see* § 174.104). Packages of Division 1.3 materials and Division 1.2 (explosive) materials must be blocked and braced to prevent their shifting and possible damage due to shifting of other freight during transportation. For recommended methods of blocking and bracing see the Intermodal Loading Guide for Products in Closed Trailers and Containers (*see* Table 1 to § 171.7 of this subchapter).

* * * * *

■ 71. In § 174.115, revise paragraph (a) to read as follows:

§ 174.115 Loading Division 1.4 (explosive) materials.

(a) Division 1.4 (explosive) materials may be loaded into any closed car in good condition, or into any container car in good condition. Car certificates are not required. Packages of Division 1.4 (explosive) materials must be blocked and braced to prevent their shifting and possible damage due to shifting of other freight during transportation. For methods of recommended loading and bracing see the Intermodal Loading Guide for Products in Closed Trailers and Containers (see Table 1 to § 171.7 of this subchapter).

* * * * *

■ 72. In § 174.290, revise paragraphs (h) and (i) to read as follows:

§ 174.290 Materials extremely poisonous by inhalation shipped by, for, or to the Department of Defense.

* * * * *

(h) When a material extremely poisonous by inhalation is transported in drums in a boxcar, they must be loaded from ends of the car toward the space between the car doors, and there braced by center gates and wedges.

(i) The doorways of a boxcar in which a material poisonous by inhalation is being transported must be protected.

PART 175—CARRIAGE BY AIRCRAFT

■ 73. The authority citation for part 175 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 44701; 49 CFR 1.81 and 1.97.

■ 74. In § 175.1, revise the section heading and paragraph (a) to read as follows:

§ 175.1 Purpose, scope, and applicability.

(a) This part prescribes the requirements that apply to the transportation of hazardous materials in commerce aboard (including attached to or suspended from) an aircraft. The requirements in this part are in addition to other requirements contained in parts 171, 172, 173, 178, and 180 of this subchapter.

* * * * *

■ 75. In § 175.9, revise paragraph (a) and paragraph (b)(6) introductory text to read as follows:

§ 175.9 Special aircraft operations.

(a) This section applies to rotorcraft external load operations transporting hazardous material on board, attached to, or suspended from an aircraft. Operators must have all applicable requirements prescribed in 14 CFR part 133 approved by the FAA Administrator prior to accepting or transporting hazardous material. In addition, rotorcraft external load operations must be approved by the Associate Administrator prior to the initiation of such operations.

(b) * * *

(6) Hazardous materials that are loaded and carried on or in cargo only aircraft, and that are to be dispensed or expended during flight for weather control, environmental restoration or protection, forest preservation and protection, flood control, avalanche control, landslide clearance, or ice jam control purposes, when the following requirements are met:

* * * * *

PART 176—CARRIAGE BY VESSEL

■ 76. The authority citation for part 176 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 44701; 49 CFR 1.81 and 1.97.

§ 176.11 [Amended]

■ 77. In § 176.11, remove and reserve paragraph (e).

PART 177—CARRIAGE BY PUBLIC HIGHWAY

■ 78. The authority citation for part 177 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 44701; sec. 112 of Pub. L. 103–311, 108 Stat. 1673, 1676 (1994); sec. 32509 of Pub. L. 112–141, 126 Stat. 405, 805 (2012); 49 CFR 1.81 and 1.97.

■ 79. In § 177.817, revise paragraph (d) to read as follows:

§ 177.817 Shipping papers.

* * * * *

(d) *Applicability.* This section does not apply to a material that is excepted from shipping paper requirements as specified in § 172.200 of this subchapter.

* * * * *

■ 80. In § 177.835, revise the section heading to read as follows:

§ 177.835 Class 1 (explosive) materials.

* * * * *

■ 81. In § 177.837, revise the section heading to read as follows:

§ 177.837 Class 3 (flammable liquid) materials.

* * * * *

■ 82. In § 177.841, revise the section heading to read as follows:

§ 177.841 Division 6.1 (poisonous) materials and Division 2.3 (poisonous gas) materials.

* * * * *

■ 83. In § 177.842, revise paragraph (b)(2) introductory text to read as follows:

§ 177.842 Class 7 (radioactive) material.

* * * * *

(b) * * *

(2) Where more than one group of packages is present in any single storage location, a single group may not have a total transport index greater than 50. Each group of packages must be handled and stored together no closer than 6 m (20 feet) (measured edge to edge) to any other group. The following table is to be used in accordance with the provisions of paragraph (b) of this section:

* * * * *

■ 84. In § 177.848, revise paragraph (e)(6) to read as follows:

§ 177.848 Segregation of hazardous materials.

* * * * *

(e) * * *

(6) When the § 172.101 table or § 172.402 of this subchapter requires a package to bear a subsidiary hazard label, segregation appropriate to the subsidiary hazard must be applied when that segregation is more restrictive than that required by the primary hazard. However, hazardous materials of the same class may be stored together without regard to segregation required for any secondary hazard if the materials are not capable of reacting dangerously with each other and causing combustion or dangerous evolution of heat, evolution of flammable, poisonous, or asphyxiant gases, or formation of corrosive or unstable materials.

* * * * *

PART 178—SPECIFICATIONS FOR PACKAGINGS

■ 85. The authority citation for part 178 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 44701; 49 CFR 1.81 and 1.97.

■ 86. In § 178.50, revise paragraph (a) to read as follows:

§ 178.50 Specification 4B welded or brazed steel cylinders.

(a) *Type, size, pressure, and application.* A DOT 4B is a welded or brazed steel cylinder with water capacity (nominal) not over 1,000 pounds and a service pressure of at least 150 but not over 500 psig. Longitudinal seams must be forged lap-welded or brazed. Cylinders closed in by spinning process are not authorized.

* * * * *

■ 87. In § 178.337–1, revise the last sentence of paragraph (f) to read as follows:

§ 178.337–1 General requirements.

* * * * *

(f) * * * The postweld heat treatment must be as prescribed in Section VIII of the ASME Code, but in no event at less than 1,050 °F cargo tank metal temperature.

* * * * *

■ 88. In 178.338–10, revise paragraph (c)(2) to read as follows:

§ 178.338–10 Accident damage protection.

(c) * * *

(2) Conform to the requirements of § 178.345–8(d).

* * * * *

■ 89. In 178.601, revise paragraph (g)(2)(vi) to read as follows:

§ 178.601 General requirements.

* * * * *

(g) * * *

(2) * * *

(vi) When the outer packaging is intended to contain inner packagings for liquids and is not leakproof or is intended to contain inner packagings for solids and is not siftproof, a means of containing any liquid or solid contents in the event of leakage must be provided in the form of a leakproof liner, plastic bag, or other equally efficient means of

containment. For packagings containing liquids, the absorbent material required in paragraph (g)(2)(v) of this section must be placed inside as the means of containing liquid contents; and

* * * * *

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

■ 90. The authority citation for part 180 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 44701; 49 CFR 1.81 and 1.97.

■ 91. In § 180.507, revise paragraph (b) to read as follows:

§ 180.507 Qualification of tank cars.

* * * * *

(b)(1) Tank cars prescribed in the following table are no longer authorized for construction but may remain in hazardous materials service provided they conform to all applicable safety requirements of this subchapter:

TABLE 1 TO PARAGRAPH (b)(1)

Specification prescribed in the current regulations	Other specifications permitted	Notes
105A200W	105A100W	1
105A200ALW	105A100ALW	1

Note 1 to Table 1 to paragraph (b)(1): Tanks built as Specification DOT 105A100W or DOT 105A100ALW may be altered and converted to DOT 105A200W and DOT 105A200ALW, respectively.

(2) [Reserved]

(3) Specification DOT–113A175W, DOT–113C60W, DOT–113D60W, and DOT–113D120W tank cars may continue in use, but new construction is not authorized.

(4) Class DOT 105A and 105S tank cars used to transport hydrogen chloride, refrigerated liquid under the terms of DOT–E 3992 may continue in service, but new construction is not authorized.

(5) Specification DOT–103A–ALW, 103AW, 103ALW, 103ANW, 103BW, 103CW, 103DW, 103EW, and 104W tank cars may continue in use, but new construction is not authorized.

■ 92. In § 180.605, revise the section heading and paragraph (b)(5) to read as follows:

§ 180.605 Requirements for periodic testing, inspection, and repair of portable tanks.

(b) * * *

(5) The portable tank is in an unsafe operating condition.

* * * * *

Issued in Washington, DC, on December 6, 2022, under the authority delegated in 49 CFR 1.97.

Tristan H. Brown,

Deputy Administrator, Pipeline and Hazardous Materials Safety Administration.

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